

# **Exhibit 3**

U.S. Department of Justice  
Drug Enforcement Administration

REPORT OF INVESTIGATION

Page 1 of 8

|   |   |               |  |                     |
|---|---|---------------|--|---------------------|
| 1. Program Code   | 2. Cross File<br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | Related Files | 3. File No.<br>[REDACTED]  | 4. G-DEP Identifier |
| 5. By: Michael D. Kupchick, DI<br>At: Pittsburgh DO   |   |               | 6. File Title<br>HBC Service Co. - 601A Meadowlands Blvd., Wash., PA 15301 |                     |
| 7. <input type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed<br><input type="checkbox"/> Action Requested By: |   |               | 8. Date Prepared<br>05-20-2011   |                     |
| 9. Other Officers: DI Vincent Tomei   |   |               |  |                     |
| 10. Report Re: Cyclic CYCLIC INVESTIGATION AND CASE CLOSING [REDACTED]  |   |               |  |                     |

SYNOPSIS

On May 13, 2011, pursuant to the Pittsburgh District Office Cyclic Workplan for FY-2011, Investigators Michael Kupchick and Vincent Tomei conducted an on-site regulatory investigation of HBC SERVICE COMPANY, Inc., located at 601 Meadowland Boulevard, Washington, PA 15301.

HBC SERVICE COMPANY is registered with DEA as a chemical handler under DEA# 001753HVY to distribute over-the-counter List I chemicals pseudoephedrine and ephedrine.

This investigation was initiated on May 13, 2011, and concluded on the same date with a meeting with management.

With respect to the requirements of a List I chemical distributor, no violations of 21 Code of Federal Regulations were uncovered. This case is closed.

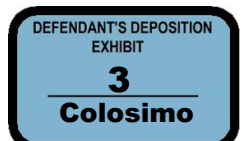
|                               |   |                        |
|-------------------------------|---|------------------------|
| 11. Distribution:<br>Division | 12. Signature (Agent)<br><br>Michael D. Kupchick, DI    | 13. Date<br>05-23-2011 |
| District                      | 14. Approved (Name and Title)<br>/s/ Kurt G Dittmer, GS | 15. Date<br>05-25-2011 |
| Other [REDACTED]              |   |                        |

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**ENCLOSURES**

1. DEA Form 82, Notice of Inspection
2. DEA Certificate of Registration 001753HVY
3. PA Department of Health certificate
4. WVA certificate
5. Ohio certificate
6. Maryland certificate
7. Product List
8. Supplier List
9. Customer List
10. Purchase Orders
11. Invoices
12. Receiving Report
13. Product Inventory on 5/13/2011

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## DETAILS

### 1. BASIS FOR INVESTIGATION

On May 13, 2011, pursuant to the Pittsburgh District Office Cyclic Workplan FY 2011, Investigators Michael Kupchick and Vincent Tomei conducted an on-site regulatory investigation of HBC SERVICE COMPANY, registered with DEA as a distributor of OTC List I chemicals pseudoephedrine and ephedrine.

### 2. SUBJECT FIRM BACKGROUND

HBC SERVICE COMPANY, located at 601 Meadowlands Boulevard, Washington, PA, 15301, was approved as a chemical distributor on August 27, 1997, and was assigned DEA Registration Number 001753HVY. The subject firm was last the subject of a regulatory investigation in February 5, 2008 (see ROI [REDACTED] dated 2-11-08). No violations were uncovered during this investigation.

HBC (Health and Beauty Care) SERVICE COMPANY is a division of Giant Eagle Super Market Corporation, with corporate headquarters at 101 Kappa Drive, Pittsburgh, PA. The subject firm distributes general merchandise, health and beauty aids, and over-the-counter products containing List I chemicals to approximately 150 Giant Eagle supermarkets located in Pennsylvania, West Virginia, Ohio, and Maryland. The firm also distributes these products to other independent supermarkets located in these states, such as Sparkle Super Markets.

The subject firm is licensed with the Pennsylvania Department of Health as a distributor of non-prescription drugs under Certificate Number 3000008128, expiration date March, 2012.

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HBC is also licensed in West Virginia, certificate # 1022-8050, with an expiration date of 6-30-11; Ohio # 00962, expiration 6-30-11; and Maryland # 078801, 6-30-2011.

A query of NADDIS and CHEMS did not reveal any negative information regarding the subject firm.

### 3. PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

On May 13, 2011, Investigators Kupchick and Tomei presented their credentials and a Notice of Inspection (DEA Form 82) to Walter DURR, Distribution Operations Manager, for the subject firm. The investigators advised DURR of the firm's rights to not have an administrative inspection made without an administrative inspection warrant. DURR then read and signed the DEA Form 82, giving his consent for the inspection to proceed. DURR stated that he is responsible for the firm's recordkeeping with respect to List I chemicals.

### 4. PRINCIPALS OF THE FIRM

Lora Karet, President and Chief Operating Officer  
Larry Baldauf, Senior Vice President of Distribution  
Robert Schreck, Vice President of Distribution  
Walter Durr, Distribution Operations Manager

NADDIS queries on these individuals did not reveal any negative information.

### 5. RECORDKEEPING

The investigators reviewed acquisition documents, inventory records, and distribution records for the firm's OTC products containing List I chemicals. Investigators also reviewed the current customer database. A review of various distribution invoices reveals that HBC SERVICE COMPANY

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is recording distributions in accordance with the requirements set forth in 21 CFR Part 1310.

All pertinent information with regard to recordkeeping was discussed with Mr. DURR. Suspicious orders and large quantity order notification requirements were also discussed. DURR stated that he understood these requirements.

DURR provided the investigators with a list of their distributed items which contain List I chemicals, primarily pseudoephedrine. A review of the products indicated that, with the exception of items manufactured by Giant Eagle Corporation, all products were "brand name." There were no "off label" items distributed.

According to DURR, all of the firm's products, including List I chemicals, are counted four times per month. He indicated that the firm's inventory control system is able to determine the identity of the employee who picked a particular customer order. He stated that the firm has not had any thefts of products containing List I chemicals since they were initially registered with DEA in 1997.

DURR provided investigators with a list of suppliers of List I chemical products and a list of their chemical product customers.

#### 6. SECURITY

HBC SERVICE COMPANY is the sole occupant of a 305,000 square foot warehouse (constructed of concrete and steel) located within a light industrial park in Washington County. A sign at the entrance to the property identifies the tenant as HBC Service Company - nothing that would indicate the presence of List I chemicals. The firm operates five days per week, 24 hours per day. There are approximately 200 employees working varied hours.

A visual inspection of the facility revealed passive infrared motion detectors and magnetic contact switches (for all exterior doors, including shipping and receiving doors) were strategically located throughout the firm, appearing to provide adequate security coverage. Glass break

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sensors are located in all rooms with exterior windows. Surveillance cameras are positioned to monitor the employee entrance and receiving door 24 hours per day; video footage is stored for a period of 30 days. The exterior of the warehouse is illuminated from dusk to dawn.

All employees are required to use a radio frequency security card to enter and leave the warehouse. Through this device, the subject firm is able to identify the date and time of employee ingress and egress.

The firm's electronic security is monitored by Sonotrol Security Company. DURR advised the investigators that when an alarm sensor is activated in the firm, a signal is transmitted to Sonotrol, who then notifies the North Strabane Township Police Department. After the police department is notified, Sonotrol will call a representative from the subject firm. According to DURR, the firm has not had any break-ins since they were registered by DEA in 1997. When an alarm is activated, an audible alarm can be heard throughout the warehouse.

DURR stated that in the event of a power outage, the firm's electronic security is maintained through battery backup.

Andrew DURR stated that all warehouse employees are initially hired through Kelly Services, a temporary employment agency. Before an employee is hired, a criminal history background check is conducted. He stated that the firm has a "zero tolerance" policy with respect to employee pilferage; an employee caught stealing merchandise is immediately terminated from employment.

The subject firm's security appeared to be adequate.

#### 7. DISCUSSION WITH MANAGEMENT

On May 13, 2011, at the conclusion of the inspection, Investigators Kupchick and Tomei met with DURR. The investigators advised DURR that the firm appeared to be in compliance with 21 CFR Part 1310.

Investigators advised DURR that pseudoephedrine and ephedrine are being used as immediate precursors for manufacturing methamphetamine.

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Investigators also advised DURR that all suspicious orders must be reported to the Pittsburgh D.O.

8. INTELLIGENCE

Mr. DURR was not able to provide the investigators with any relevant intelligence relating to the diversion of List I chemicals.

9. CUSTOMER VERIFICATIONS

Sales verifications of List I chemicals were conducted on May 23, 2011 with Giant Eagle Village Square, 700 Oxford Drive, Bethel Park, PA 15102. No additional actions are required in this investigation; therefore, this case is closed.

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**INDEXING**

1. HBC SERVICE COMPANY [REDACTED]

Regulatory investigation, no violations

2. DURR, Walter [REDACTED]

No update needed

3. SCHRECK, Robert [REDACTED]

No update needed

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| 7. <input checked="" type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed<br><input type="checkbox"/> Action Requested By: | <input type="checkbox"/> |               | 8. Date Prepared<br>05-20-2011   |                     |
| 9. Other Officers: DI Vincent Tomei  |                          |               |  |                     |
| 10. Report Re: Cyclic Investigation and Case Closing [REDACTED]  |                          |               |  |                     |

**SYNOPSIS**

On May 13, 2011, pursuant to the Pittsburgh District Office Cyclic Workplan for FY 2011, Investigators Michael Kupchick and Vincent Tomei conducted an on-site regulatory investigation of HBC SERVICE COMPANY, Inc., located at 601 Meadowland Boulevard, Washington, PA, 15301.

HBC SERVICE COMPANY is registered with DEA as a distributor under DEA# RH0389773 to distribute Schedule III thru V controlled substances. This investigation was initiated on May 13, 2011, and concluded on May 17, 2011, with a meeting with management.

This investigation revealed no discrepancies with respect to security. This audit did reveal minor discrepancies with recordkeeping and the actual count of controlled substances audited. However, the discrepancies were within the acceptable range. Therefore, this case is closed.

|                               |   |                        |
|-------------------------------|---|------------------------|
| 11. Distribution:<br>Division | 12. Signature (Agent)<br><br>Michael D. Kupchick, DI    | 13. Date<br>06-08-2011 |
| District                      | 14. Approved (Name and Title)<br>/s/ Kurt G Dittmer, GS | 15. Date<br>06-10-2011 |
| Other [REDACTED]              |   |                        |

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ENCLOSURES

-  
-

1. DEA Form 82, Notice of Inspection
2. DEA Certificate of Registration RH0389773
3. PA Department of Health certificate
4. Ohio State Board of Pharmacy Certificate
5. Letter requesting central record keeping
6. Product List
7. List of Personnel with Access to Controlled Substances
8. ARCOS Printout
9. Computation Chart
10. Closing Inventory
11. Product Inventory 5/13/2011
12. Sales Records
13. Customer List
14. Purchase Records
15. Supplier List
16. Inventory Records
17. Receiving Report
18. HBC Pharmacy Operations and Procedures Manual
19. Floor Plan

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## DETAILS

### 1. BASIS OF INVESTIGATION

On May 13, 2011, pursuant to the Pittsburgh District Office Cyclic Workplan for FY 2011, Investigators Michael Kupchick and Vincent Tomei conducted an on-site regulatory investigation of HBC SERVICE COMPANY, Inc., located at 601 Meadowland Boulevard, Washington, PA, 15301.

HBC SERVICE COMPANY is registered with DEA as a distributor under DEA# RH0389773 to distribute Schedule III thru V controlled substances. This investigation was initiated on May 13, 2011, and concluded on May 17, 2011 with a meeting with management.

### 2. SUBJECT FIRM'S BACKGROUND

HBC (Health and Beauty Care) SERVICE COMPANY, located at 601 Meadowlands Boulevard, Washington, PA, 15301, is a division of GIANT EAGLE, INC., with corporate headquarters at 101 Kappa Drive, Pittsburgh, PA, 15238. The subject firm distributes general merchandise, health and beauty aids, over-the-counter products containing List I chemicals and Scheduled III - V controlled substances to approximately 210 Giant Eagle supermarkets located in Pennsylvania, West Virginia, Ohio, and Maryland.

HBC SERVICE COMPANY, hereinafter referred to as HBC, was approved as a distributor of List I chemicals on August 27, 1997, and was assigned DEA Registration Number 001753HVY. The subject firm was the subject of in-depth cyclic investigations in 2002 [REDACTED], 2004 [REDACTED], and 2008 [REDACTED]. No violations were uncovered during these investigations. HBC was approved as a distributor of controlled substances in October 2009.

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HBC is licensed with the Commonwealth of Pennsylvania, Department of Health, as a distributor of prescription medicine, Certificate Number 3000008128. (See attachment)

### 3. PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

On May 13, 2011, Investigators Kupchick and Tomei presented their credentials and a Notice of Inspection (DEA Form 82) to Walter DURR, Distribution Operations Manager, for the subject firm. The investigators advised DURR of the firm's right to not have an administrative inspection made without an administrative inspection warrant. DURR then read and signed the DEA Form 82, giving his consent for the inspection to proceed. DURR stated that he is responsible for the firm's recordkeeping with respect to List I chemicals.

### 4. PRINCIPALS OF THE FIRM

Lora Karet, President and Chief Operating Officer  
Larry Baldauf, Senior Vice President of Distribution  
Robert Schreck, Vice President of Distribution  
Walter Durr, Distribution Operations Manager

NADDIS queries on these individuals did not reveal any negative information.

### 5. SCOPE OF INVESTIGATION

The on-site portion of the investigation commenced on May 13, 2011, and concluded on May 17, 2011, with a meeting with management.

An accountability of zalepon 10mg, temazepam 30mg, butalbital/APAP 50/325, promethazine/codeine 6.25/10, hydrocodone 10/300, hydrocodone 7.5/650 and hydrocodone 7.5/200 was conducted for the period January 1, 2011 (COB), through May 13, 2011 (BOB).

The results of this audit are documented on the attached computation chart. This accountability audit revealed overages with all of the

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controlled substances. After a thorough review and analysis of the required records, it was determined that all of the controlled substances were accounted for. The discrepancies can be attributed to the fact that several databases being used to track inventory and shipments.

| Drug Name                     | Initial Inventory<br>01/01/2011 | Received | Total Accountable For | Closing Inventory<br>05/13/2011 | Sales   | Total Accounted For | Diff  | % |
|-------------------------------|---------------------------------|----------|-----------------------|---------------------------------|---------|---------------------|-------|---|
| Zalepon 10mg                  | 11,000                          | 15,600   | 26,600                | 7700                            | 19,000  | 26,700              | +100  |   |
| Temazepam 30mg                | 72,400                          | 223,200  | 295,600               | 59,100                          | 238,600 | 297,700             | +2100 |   |
| Butalbital /Apap 50/325       | 12,100                          | 7,200    | 19,300                | 700                             | 18,700  | 19,400              | +100  |   |
| Promethazine /Codeine 6.25/10 | 273,867                         | 930,864  | 1,204,731             | 271,975                         | 933,702 | 1,205,677           | +946  |   |
| Hydrocodone /Apap 10/300      | 0                               | 96,000   | 96,000                | 80,000                          | 16,000  | 96,000              | 0     | 0 |
| Hydrocodone /Apap 7.5/650     | 15,300                          | 24,000   | 39,300                | 8,600                           | 31,000  | 39,600              | +300  |   |
| Hydrocodone /Apap 7.5/200     | 8,200                           | 146,400  | 154,600               | 23,100                          | 133,100 | 156,200             | +1600 |   |

Biennial Inventory:

A biennial inventory required by Title 21 C.F.R. 1304.11 (c) was not required at this time.

Initial Inventory:

This figure was taken from the firm's daily control substance log sheet for each controlled substance selected for the audit at the close of business January 1, 2011.

Closing Inventory:

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On May 13, 2011, DI's Kupchick and Tomei conducted a closing inventory, which was witnessed and DURR.

Receiving Records:

The subject firm's receiving records consist of invoices from the distributors and drug manufacturers from whom they purchase their controlled substances. The information on the invoices contained all information as required by 21 C.F.R. 1304.22.

Sales Records:

The subject firm's sales records consist of invoices indicating the customer's name, DEA Number, invoice date, controlled substance sold, and quantity sold.

Returns to Suppliers of Controlled Substances:

Of the controlled substances selected for the audit, there were no returns to suppliers during the audit period.

6. RECORDKEEPING

Regarding the disposal of controlled substances, DURR stated HBC uses Capital Returns, a reverse distributor, to destroy expired or contaminated controlled substances.

According to DURR, HBC stores all original purchase and sales information at their corporate headquarters (Giant Eagle, Inc.) at 101 Kappa Drive, Pittsburgh, PA 15235. According to DURR, HBC keeps original records at their registered location.

7. ARCOS

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CARLSON, the firm's pharmacy manager, informed the investigators that he has submitted ARCOS reports to DEA on a quarterly basis. A query of the ARCOS database shows HBC's most recent report was submitted on 5/31/2011.

#### 8. SECURITY

HBC SERVICE COMPANY is the sole occupant of a 305,000 square foot warehouse (constructed of concrete and steel) located within the Meadowlands Industrial Park, a light industrial park in Washington County. A sign at the entrance to the property identifies the tenant as HBC Service Company - there is nothing that would indicate the presence of List I chemicals or controlled substances. The firm operates five days per week, 24 hours per day. There are approximately 150 warehouse employees working varied hours.

A visual inspection of the facility revealed passive infrared motion detectors and magnetic contact switches (for all exterior doors, including shipping and receiving doors) were strategically located throughout the firm, appearing to provide adequate security coverage. (See attached warehouse floor plan.) Glass break sensors are located in all rooms with exterior windows. Surveillance cameras are positioned to monitor the employee entrance and receiving door 24 hours per day; video footage is stored for a period of 30 days. The exterior of the warehouse is illuminated from dusk to dawn.

All employees are required to use a radio frequency security card to enter and leave the warehouse. Through this device, the subject firm is able to identify the date and time of employee ingress and egress.

The firm's electronic security is monitored by Sonotrol Security Company. DURR advised the investigators that when an alarm sensor is activated in the firm, a signal is transmitted to Sonotrol, who then notifies the South Strabane Township Police Department, located less than five minutes from the firm. After the police department is notified, Sonotrol will call a representative from the subject firm. According to DURR, the firm has not had any break-ins since they were registered by DEA in 1997 to handle List I chemicals. When an alarm is activated, an audible alarm can be heard throughout the warehouse.

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(Jul. 1996)

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DURR stated that, in the event of a power outage, the firm's electronic security is maintained through a battery backup. DURR stated that all warehouse employees are initially hired through Kelly Services, a temporary employment agency. Before an employee is hired, a criminal history background check is conducted. He stated that the firm has a "zero tolerance" policy with respect to employee pilferage, which means that an employee caught stealing merchandise is immediately terminated from employment.

All controlled substances will be stored in a steel cage measuring approximately 30' width x 40' depth x 22' height. The walls and ceiling of the cage, along with cage doors, are constructed of #10 gauge steel fabric. The door to the cage is equipped with a contact switch. The cage is also equipped with four passive infrared motion detectors. All elements of this cage meet the requirements specified in 21 CFR 1301.72(b)(4).

The security cage is located within a large room (hereinafter referred to as pharmacy room) which is attached to HBC's main warehouse. All interior doors and the one exterior door of the pharmacy room are equipped with contact switches. Passive infrared motion detectors are located throughout the pharmacy room providing adequate coverage. Sixteen security cameras are located within this room. Four security cameras monitor the exterior perimeter of this pharmacy room.

All HBC team members with access to the cage or those involved in handling the controlled substances undergo the required background checks associated to the following DEA regulations in 21 CFR Part 1300: 1301.76, 1301.90, 1301.92 and 1301.93.

Access to the pharmacy room itself is limited to HBC team members who have direct day-to-day involvement with any activity necessary to sustain the room. This is done through key fob access. Fobs will be required to enter and exit the room. No other team members can enter the room unless granted access by the pharmacy room coordinators or a member of the HBC management team. Access is granted only for business need, i.e., allowing a team member to haul away and dump a full cardboard bin, and then only after video confirmation of who is attempting to enter. Union team

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members with fob access to the room are not permitted to allow anyone to enter this room unaccompanied. Any visitor to the room must be accompanied by a member of the HBC operation's management team. It is possible that team members may have access to the pharmacy room, but will be restricted from the cage or any work process associated with handling controlled substances.

The cage inside the pharmacy room that contains the controlled substances remains locked at all times when not in use. It is permissible for the cage to be unlocked when in use as long as it is being monitored by the coordinator or a member of the management team. If unlocked, only those in compliance with the previously-mentioned DEA regulations are permitted to enter inside. Maintenance personnel are granted access for repair work, as long as they are in compliance with the regulations. Keys to unlock the cage are in possession of the HBC operation's management team only.

Exterior entrance to the pharmacy room is also controlled through fob access through a man door. Access to the exterior door is only granted to the management staff and maintenance personnel. When a carrier arrives for either pick up or delivery, a supervisor must be notified. When the supervisor arrives in the room, he or she must view the three exterior cameras before going outside to lock the vehicle in place. HBC has installed a device on the loading dock which essentially seals the garage door entrance and the back door of the delivery truck. (See attached photo.)

Therefore, when the delivery truck is backed onto the dock and the device is in place, it is impossible to gain access to the pharmacy room from the building's exterior. Once the vehicle is locked in place, the supervisor will fob back inside. The supervisor closes the exterior door before allowing the driver to enter. The supervisor ensures the holding area is secure and then scans the fob to allow the driver into the holding area. (See attached photo.) Once the exterior door is closed behind the driver, the supervisor will release the holding area door to fully allow the driver inside the pharmacy room.

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The supervisor will then unlock the padlock that secures the grade-level garage door. If the delivery contains controlled substances, the supervisor unlocks the cage so the product can be taken directly into the protected area. The reconciliation takes place inside the cage by the receiver, but excludes the driver. If the driver arrives for pick up, the supervisor follows the same steps indicated for the receiving process before allowing the driver access inside. Once either process is complete, the supervisor again reviews the video security before going outside to release the truck. If the area is clear, the supervisor goes outside and unlocks the secure gates.

On May 13, 2011, investigators tested all aspects of the firm's electronic security. The security was operational and deemed adequate.

#### 9. RECEIVING

All controlled substances are delivered to the grade-level garage door that leads directly into the pharmacy room at HBC. Each vendor is required to ship product against a Giant Eagle generated purchase order.

Each purchase order shows the "ship to" address as 601A Meadowlands Blvd, Washington, PA. Upon arrival, all controlled pharmaceuticals are immediately taken into the locked controlled cage. The counting of the controlled drugs takes place inside the cage.

HBC personnel notes any discrepancy directly on the bill of lading as it is signed. This includes overages, shortages, and damages.

#### 10. STORAGE

All controlled pharmaceuticals are maintained inside the cage at all times, from receipt through selection. This encompasses all associated tasks - receiving, storage, replenishment, and selection.

#### 11. SELECTION

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All selections are performed using Vocollect® directed activity. The Vocollect® system directs users via headset to the location and quantity of each item to select. As the selector is picking, they scan the NDC bar code of the item to ensure the exact item is being selected. This is repeated for all items until all total units are selected. (These tasks are completed one customer at a time.) The controlled substances are placed inside a #12 white paper bag with a pick list attached to the outside of the bag, for ease of customer verification upon delivery. Upon completion of the tasks inside the cage, the tasks are combined with the generic drug tasks and consolidated into the fewest shipping cartons/totes as possible. All totes are sealed, and completed totes are constructed on pallets by geographical destination. The combining of orders also takes place inside the cage.

#### 12. INVENTORY CONTROLS

In addition to the self-scan audit during selection, HBC performs random audits of at least ten percent of the total tasks being completed. After all selections complete, HBC cycle-counts all controlled substances daily as the business is run (currently Sunday through Thursday), and always prior to selecting a new billing cycle. All discrepancies are researched thoroughly in attempt to find the variance. This includes going through the totes of all completed orders (if they have not shipped yet). It also includes searching all trash receptacles and empty boxes before they are disposed. If discrepancies remain, the HBC Pharmacy Merchandising team is notified and cycle-count adjustments are made. The Pharmacy Merchandising group notifies all customers to search for any discrepancy with their inbound order.

#### 13. SHIPPING

All deliveries of pharmacy orders are performed through a dedicated third-party courier service, Prestige Delivery Systems. HBC electronically sends a barcoded file for all pharmacy orders to Prestige after all orders are released. The bar code contains carton ID and customer name and address, and is used by Prestige and HBC for proof of delivery. Prestige

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delivers directly to the pharmacy at each location while obtaining customer signature. Each customer verifies seal is intact before signing for the delivery.

If the seal is broken, the customer is required to verify all contents of controlled pharmaceuticals against the accompanying pick list. If the seal is broken and the contents of what is being presented do not match the pick list, the customer must immediately note the exception(s) to Wholesale Customer Service, Pharmacy Customer Service and HBC. The customer must also note if the white bag was sealed (stapled). If the white bag is stapled and was not tampered, an investigation will be launched back at HBC to determine what caused the discrepancy. This investigation will include a review of the self-audit bar code scan file, the video security system and the cycle count results following that day's billing run. If the white bag was tampered with, Giant Eagle Loss Prevention is also notified so they may begin an investigation that may also include the courier service.

As per 21 CFR 1301.74 (e), the firm is responsible for selecting a common or contract carrier which provides adequate security to guard against in-transit losses. The site also addresses the responsibility of the firm, when storing controlled substances in a public warehouse, to select a warehouseman which will provide adequate security to guard against storage losses. As noted below, the firm appears to comply with this site. The firm uses Prestige Delivery Systems, Inc. to ship all controlled substances. According to the website for Prestige Delivery systems ([www.prestigedelivery.com](http://www.prestigedelivery.com)), Prestige provides same day and next day delivery and logistics services to clients throughout the northeast and midwest. The website lists 38 warehouses operated by Prestige.

According to DURR, Prestige ships controlled substances for HBC in the following manner: At a pre-determined time (usually at 1 a.m.), a driver from Prestige picks up controlled substances from HBC (in sealed totes) and delivers them to one of five Prestige warehouses:

Pittsburgh, PA: 161 Spring Run Road Ext, Bldg 2, Coraopolis, PA 15108  
Meadville, PA: 10921 Murray Rd, Meadville, PA 16335

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Cleveland, OH: 9535 Midwest Avenue, #104, Cleveland, OH 44125

Columbus, OH: 4279 Directors Blvd, Groveport, OH 43125

Akron, OH: 4240 Sunnybrooke Rd, Kent, OH 44240

When the orders are delivered to these warehouses, the totes containing the controlled substances are immediately unloaded and placed into a steel cage, which is bolted to the floor and whose ceiling is also constructed of steel fencing. When the totes are segregated by their final destination, the totes are then loaded onto Prestige delivery trucks and delivered, either to the pharmacy or to one of the five warehouses for further segregation. The controlled substances are stored at each warehouse for only one to three hours. Controlled substances are not stored at the warehouse overnight, or when the warehouse is closed. Prestige maintains the proper chain of custody of controlled substances from pickups at HBC to deliveries to pharmacies.

All Prestige warehouses, including their storage cages, are monitored by cameras placed throughout the warehouses. Prestige policy is to weekly audit (random and unannounced) 15 percent of all Prestige drivers. Among other things, this audit consists of ensuring delivery trucks are locked at all times and that drivers are maintaining proper chain of custody of merchandise.

DURR informed DI's Kupchick and Tomei that the following individuals will have access to HBC's storage cage:

| Name                      | Social Security Number | Birthdate  |
|---------------------------|------------------------|------------|
| Management                |                        |            |
| Kristie Abercrombie-Hilty | [REDACTED]             | [REDACTED] |
| Jeff Biddle               | [REDACTED]             | [REDACTED] |
| William Cudlipp           | [REDACTED]             | [REDACTED] |
| Walter Durr               | [REDACTED]             | [REDACTED] |
| William Hevia             | [REDACTED]             | [REDACTED] |
| Steven Post               | [REDACTED]             | [REDACTED] |

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|                     |  |  |
|---------------------|--|--|
| Matthew Rogos       |  |  |
| Stephanie Summers   |  |  |
| Anthony Tilford Jr. |  |  |
| <b>Support</b>      |  |  |
| Justin Baer         |  |  |
| Brian Becquet       |  |  |
| Daniel Bowman       |  |  |
| William Cooper      |  |  |
| Nathan Danforth     |  |  |
| Julie Dean          |  |  |
| Shawna Flynn        |  |  |
| Christy Hart        |  |  |
| Joyce McConn        |  |  |
| Richard Poland III  |  |  |
| Charles Prigg       |  |  |
| John Vinski         |  |  |
| Becky Walton        |  |  |

DURR also stated that an additional 45 employees have the ability to enter the controlled substance area, if needed. DURR stated that this is based on the employee's union requirements. DURR further stated that any one of these 45 employees may be required to work in the controlled substance area to fill vacancies and emergencies. According to DURR, none of the additional 45 employees have, so far, worked in the controlled substance area.

NADDIS checks on the individuals listed above did not reveal negative information.

#### 14. MEETING WITH MANAGEMENT

On May 17, 2011, Diversion Investigators Kupchick and Tomei traveled to Giant Eagle Corporate Headquarters located in RIDC Park, Pittsburgh, PA, to review records and meet with management to discuss the results of the audit. During this meeting, investigators met with Gregory CARLSON,

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Director of Pharmacy Sourcing for HBC. During this meeting, investigators explained to CARLSON the overages, as discovered in the audit. The investigators explained to CARLSON what information they need to successfully conduct an audit. CARLSON stated that HBC will incorporate this required information into their accounting and audit programs, so to provide more accurate accountability.

#### 15. VERIFICATIONS

On June 8, 2011, the Giant Eagle Pharmacy located in Kennedy Township was contacted to verify an order shipped by HBC SERVICE COMPANY, on April 2, 2011. The pharmacist on duty confirmed the purchase of one 100-tablet bottle of temazepam 30mg on that date, received from HBC SERVICE COMPANY.

On June 8, 2011, the Giant Eagle Pharmacy located in Robinson Township was contacted to verify an order shipped by HBC SERVICE COMPANY, on March 31, 2011. The pharmacist on duty confirmed the purchase of one 100-tablet bottle of temazepam 30mg on that date, received from HBC SERVICE COMPANY.

HBC SERVICE COMPANY'S controlled substance purchases were verified via wholesale shipping records and invoices of Mylan and Pfizer for the products selected for this audit. These quantities were also confirmed through DEA's ARCOS reporting system for the accountability period.

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**INDEXING**

1. HBC SERVICE COMPANY [REDACTED]

\* Regulatory investigation, no violations.

2. CARLSON, Gregory L [REDACTED]

\* No update needed

3. ZELASKI, John [REDACTED]

\* No update needed

4. DURR, Walter [REDACTED]

\* No update needed

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U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

NOTICE OF INSPECTION  
OF CONTROLLED PREMISES

|              |
|--------------|
| DEA USE ONLY |
| FILE NUMBER  |

|   |                                   |
|---|-----------------------------------|
| NAME OF INDIVIDUAL<br><b>MATTHEW ROGOS</b>          | TITLE<br><b>OPERATIONS MGR</b>    |
| NAME OF CONTROLLED PREMISES<br>HBC Services Company | DEA REGISTRATION NO.<br>RH0389773 |
| NUMBER AND STREET<br>601 A Meadowlands Blvd.        | DATE<br>08-12-2013                |
| CITY AND STATE<br>Washington, PA                    | ZIP CODE<br>15301                 |
|   | TIME (initial inspection)         |

**STATEMENT OF RIGHTS**

1. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.
2. You have the right to refuse to consent to this inspection.
3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution.
4. You shall be presented with a copy of this Notice of Inspection.
5. You may withdraw your consent at any time during the course of the inspection.

**ACKNOWLEDGMENT AND CONSENT**

I, John M. Conlon, have been advised of the above Statement of Rights

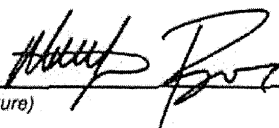
by DEA Investigator JohnM. Conlon, who  
(Name)  
(Title and Name)

has identified himself/herself to me with his/her credentials and presented me with this Notice of Inspection containing a copy of sections 302(f) and 510(a), (b) and (c) of the Controlled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 880(a), (b) and (c)), printed hereon, \* authorizing an inspection of the above-described controlled premises. I hereby acknowledge receipt of this Notice of Inspection. In

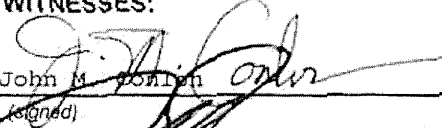

addition, I hereby certify that I am the OPERATIONS MANAGER  
(President) (Manager) (Owner)

for the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.

I understand what my rights are concerning inspection. No threats or promises have been made to me and no pressure of any kind has been used against me. I voluntarily give consent for inspection of these controlled premises.

  
(Signature)  
08-12-2013  
(Date)

**WITNESSES:**

 08-12-2013  
(signed) (date)  
 08-12-2013  
(signed) (date)

\* See Reverse

FORM DEA-82 (11-01) Previous editions are obsolete



# Certificate of Registration

**Certificate No.** 3000008128

(A certificate starting with a number 4, 5 or 6 does not permit the possession or sale of controlled substances or prescription drugs.)

**Category:**

Distributor (Prescription)

HBC SERVICE COMPANY  
DIV. OF GIANT EAGLE, INC.  
601 MEADOWLANDS BOULEVARD  
WASHINGTON, PA 15301

**Drug & Device Registration**

132 Kline Plaza  
Suite A  
Harrisburg, PA 17104  
(717) 783-1379

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: March 09, 2007  
Expiration Date: The Last Day of March, 2014

A handwritten signature in cursive script.

Anna Marie Sossong  
Deputy Secretary for Quality Assurance



**pennsylvania**  
DEPARTMENT OF HEALTH

A handwritten signature in cursive script.

Michael Wolf  
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.





## Board of Pharmacy

### WHOLESALE DRUG DISTRIBUTOR PERMIT

July 1, 2013 - June 30, 2014 - Date Issued: May 22, 2013

HBC ServiceCompany

Division of Giant Eagle, Inc.  
601 Meadowlands Blvd.  
Washington, PA 15301

LICENSE # WD0558704

DEA # RH0389773



## Board of Pharmacy

### CONTROLLED SUBSTANCE PERMIT

July 1, 2013 - June 30, 2014 - Date Issued: August 07, 2013

HBC ServiceCompany

Division of Giant Eagle, Inc.  
601 Meadowlands Blvd.  
Washington, PA 15301

LICENSE # MI0000275

DEA # RH0389773

Schedule III Narcotic  
Schedule III Non-Narcotic  
Schedule IV All  
Schedule V All

State of Ohio

## STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, Ohio 43215-6126 TEL: 614/466-4143 FAX: 614/752-4836 EML: licensing@bop.ohio.gov

Be it known that the DISTRIBUTOR OF CONTROLLED SUBSTANCES named below has given satisfactory evidence that all statutory requirements (WHOLESALER -- ORC Sections 3719.021 & 3719.03; MANUFACTURER -- ORC Sections 3719.02 & 3719.03) have been met, is duly registered, and is entitled to distribute controlled substances in the state of Ohio until the expiration date of JUNE 30, 2014:

Identification Number WCSW . 2458

0464

RESPONSIBLE PERSON:

GREGORY L. CARLSON PDM

HBC SERVICE COMPANY, AN OPERATING  
DIVISION OF GIANT EAGLE, INC.  
601 MEADOWLANDS BLVD.  
WASHINGTON PA 15301

SIGNATURE OF RESPONSIBLE PERSON

Any change of responsible person must be reported within thirty days on a "Notification of Change of Responsible Person" form.

Before change of name, address, or ownership, immediately notify the Licensing Department of the State Board of Pharmacy.

CLASS: Controlled Substance Wholesaler

SIGN AND KEEP IN A READILY RETRIEVABLE LOCATION AT THIS ADDRESS

State of Ohio

## STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, Ohio 43215-6126 TEL: 614/466-4143 FAX: 614/752-4836 EML: licensing@bop.ohio.gov

Be it known that the WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS named below has given satisfactory evidence that all statutory requirements (ORC Sections 4729.52 & 4729.53) have been met, is duly registered, and is entitled to distribute dangerous drugs at wholesale in the state of Ohio until the expiration date of JUNE 30, 2014:

Identification Number WCOR . 011702550

01206

RESPONSIBLE PERSON:

GREGORY L. CARLSON PDM

HBC SERVICE COMPANY, AN OPERATING  
DIVISION OF GIANT EAGLE, INC.  
601 MEADOWLANDS BLVD.  
WASHINGTON PA 15301

SIGNATURE OF RESPONSIBLE PERSON

Any change of responsible person must be reported within thirty days on a "Notification of Change of Responsible Person" form.

Before change of name, address, or ownership, immediately notify the Licensing Department of the State Board of Pharmacy.

CLASS: Wholesale DDD - Wholesale W/in Own Corp - Category Three

## COMPUTATION CHART

FIRM/DEA# RH0389773FILE # HBCAUDIT PERIOD 2/11/13 to 8/12/13

C o B

| (SIZE) | DRUG                    | B.O.B.<br>INITIAL<br>INV. | RECEIPT | TOTAL<br>ACCOUNT. | B.O.B.<br>CLOSING<br>INV. | SALES | TOTAL<br>ACCOUNT | DIFF. # | % |
|--------|-------------------------|---------------------------|---------|-------------------|---------------------------|-------|------------------|---------|---|
| 500's  | Hydro 5mg               | 0                         | 11,412  | 11412             | 1692                      | 9720  | 11412            | 0       | 0 |
| 100's  | Hydro 7.5mg             | 534                       | 5568    | 6102              | 411                       | 5691  | 6102             | 0       | 0 |
| 100's  | Hydro 10mg              | 0                         | 18264   | 18264             | 2572                      | 15692 | 18264            | 0       | 0 |
| 60's   | ALPRAZ 1mg              | 0                         | 120     | 120               | 27                        | 93    | 120              | 0       | 0 |
| 100's  | ALPRAZ 2mg              | 194                       | 2496    | 2690              | 417                       | 2273  | 2690             | 0       | 0 |
| 100's  | AP/COD 60mg             | 162                       | 984     | 1146              | 146                       | 1000  | 1146             | 0       | 0 |
| 100's  | CHLORD 10mg             | 0                         | 396     | 396               | 97                        | 299   | 396              | 0       | 0 |
| 734 mL | Apap Codexl<br>12mg/5mL | 108                       | 468     | 576               | 63                        | 513   | 576              | 0       | 0 |

## Pharmacy Warehouse Inventory Adjustments

Registrant: HBC Service Company DEA# RH0389773

From beginning of business day 2/11/2013 to close of business day 8/12/2013

Selected Items: 181644 - HYDROCO/APAP 5-500MG TAB - 00591034905 - 500 TAB

| Drug Name, Strength, Form        | Sc<br>hd | HBC<br>Item # | NDC #       | Invoice<br>Date | Adjustment Reason | Adjustment<br>Quantity |
|----------------------------------|----------|---------------|-------------|-----------------|-------------------|------------------------|
| HYDROCO/APAP 5-500MG TAB 500 TAB | 3        | 181644        | 00591034905 | 3/12/2013       | Damage Destroy    | -1                     |
| HYDROCO/APAP 5-500MG TAB 500 TAB | 3        | 181644        | 00591034905 | 3/31/2013       | Damage Destroy    | -11                    |
| HYDROCO/APAP 5-500MG TAB 500 TAB | 3        | 181644        | 00591034905 | 4/23/2013       | Damage Destroy    | -2                     |
| HYDROCO/APAP 5-500MG TAB 500 TAB | 3        | 181644        | 00591034905 | 5/8/2013        | Damage Destroy    | -1                     |
| HYDROCO/APAP 5-500MG TAB 500 TAB | 3        | 181644        | 00591034905 | 7/7/2013        | Damage Destroy    | -9                     |

Handbill adjustments are included in NDC audit reports as quantities shipped.

Report Executed: 8/12/2013 7:44:27 PM

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US-DEA-00030610



# DEA BIENNIAL REPORT

11/1/2012

## NDC Audit Sheet

Registrant: HBC Service Company  
 Initial Inventory Date: 11/1/2012 Beginning of Business  
 Closing Inventory Date: 11/2/2012 Close of Business

DEA# RH0389773

Selected items: All Controlled Items in schedule: 3 4 5

|                                       |           |               |             | Inventory Dates |           |                       |              |                 |
|---------------------------------------|-----------|---------------|-------------|-----------------|-----------|-----------------------|--------------|-----------------|
| Drug Name, Strength, Form             | Sch<br>hd | HBC<br>Item # | NDC #       | Min             | Max       | Initial Inven<br>tory | Var<br>Units | Dollar<br>Value |
| ALPRAZOLAM 0.25MG TAB - 500 TAB       | 4         | 145045        | 00781106105 | 11/1/2012       | 11/2/2012 | 852                   | 0            | \$2,982.00      |
| ALPRAZOLAM 0.5MG TAB - 500 TAB        | 4         | 144758        | 00781107705 | 11/1/2012       | 11/2/2012 | 1,327                 | 0            | \$5,308.00      |
| ALPRAZOLAM 1MG TAB - 500 TAB          | 4         | 144485        | 47335060513 | 11/1/2012       | 11/2/2012 | 519                   | 0            | \$2,439.24      |
| ALPRAZOLAM 2MG TAB - 100 TAB          | 4         | 144956        | 47335060688 | 11/1/2012       | 11/2/2012 | 399                   | 0            | \$917.66        |
| ALPRAZOLAM ER 0.5MG TAB - 60 TAB      | 4         | 145268        | 59762005701 | 11/1/2012       | 11/2/2012 | 94                    | 0            | \$376.00        |
| ALPRAZOLAM ER 1MG TAB - 60 TAB        | 4         | 144881        | 59762005901 | 11/1/2012       | 11/2/2012 | 142                   | 0            | \$586.46        |
| ALPRAZOLAM ER 2MG TAB - 60 TAB        | 4         | 145177        | 59762006601 | 11/1/2012       | 11/2/2012 | 54                    | 0            | \$273.78        |
| APAP/CODEIN 120-12MG/5ML ELX - 473 ML | 5         | 145334        | 00603102058 | 11/1/2012       | 11/2/2012 | 299                   | 0            | \$1,270.75      |
| APAP/CODEIN 300/30 MG TAB - 1000 TAB  | 3         | 118398        | 00603233832 | 11/1/2012       | 11/2/2012 | 336                   | 0            | \$13,087.20     |
| APAP/CODEIN 300/60MG TAB - 100 TAB    | 3         | 118406        | 00603233921 | 11/1/2012       | 11/2/2012 | 408                   | 0            | \$3,304.80      |
| ASCOMP COD 30MG CAP - 100 CAP         | 3         | 242958        | 51991007401 | 11/1/2012       | 11/2/2012 | 169                   | 0            | \$5,915.00      |
| BUT/APAP/CAF CODEIN CAP - 100 CAP     | 3         | 144386        | 00603255321 | 11/1/2012       | 11/2/2012 | 116                   | 0            | \$1,595.00      |
| BUT/ASA/CAFF CAP - 100 CAP            | 3         | 144931        | 00591321901 | 11/1/2012       | 11/2/2012 | 190                   | 0            | \$2,964.00      |
| BUTORPHANOL 10MG/ML SOL - 3 ML        | 4         | 118315        | 00054309036 | 11/1/2012       | 11/2/2012 | 148                   | 0            | \$999.01        |
| CARISOPRODOL 350MG TAB - 500 TAB      | 4         | 172395        | 00603258228 | 11/1/2012       | 11/2/2012 | 362                   | 0            | \$6,859.90      |
| CLONAZEPAM 0.5MG TAB - 100 TAB        | 4         | 118414        | 00603294821 | 11/1/2012       | 11/2/2012 | 3,810                 | 0            | \$4,381.50      |
| CLONAZEPAM 1MG TAB - 100 TAB          | 4         | 118422        | 00603294921 | 11/1/2012       | 11/2/2012 | 2,457                 | 0            | \$3,562.65      |
| CLONAZEPAM 2MG TAB - 100 TAB          | 4         | 118430        | 00603295021 | 11/1/2012       | 11/2/2012 | 407                   | 0            | \$895.40        |
| CLORAZ DIPOT 3.75MG TAB - 100 TAB     | 4         | 145342        | 00378003001 | 11/1/2012       | 11/2/2012 | 123                   | 0            | \$905.26        |
| CLORAZ DIPOT 7.5MG TAB - 100 TAB      | 4         | 118323        | 63304055301 | 11/1/2012       | 11/2/2012 | 147                   | 0            | \$1,309.74      |

|  |   |        |             |           |           |       |   |              |
|--|---|--------|-------------|-----------|-----------|-------|---|--------------|
| DIAZEPAM 10MG TAB - 100 TAB            | 4 | 144501 | 00172392760 | 11/1/2012 | 11/2/2012 | 762   | 0 | \$723.90     |
| DIAZEPAM 2MG TAB - 100 TAB             | 4 | 144527 | 00603321321 | 11/1/2012 | 11/2/2012 | 278   | 0 | \$381.40     |
| DIAZEPAM 5MG TAB - 500 TAB             | 4 | 118562 | 00172392670 | 11/1/2012 | 11/2/2012 | 359   | 0 | \$1,687.33   |
| DIPHEN/ATROP 2.5MG TAB - 100 TAB       | 5 | 144857 | 00378041501 | 11/1/2012 | 11/2/2012 | 1,224 | 0 | \$9,326.88   |
| EEMT 1.25-2.5MG TAB - 100 TAB          | 3 | 169599 | 53746007801 | 11/1/2012 | 11/2/2012 | 153   | 0 | \$3,060.00   |
| EEMT HS 0.625-1.25MG TAB - 100 TAB     | 3 | 169581 | 53746007701 | 11/1/2012 | 11/2/2012 | 143   | 0 | \$2,860.00   |
| GUAFENESIN DAC SOL - 473 ML            | 5 | 144014 | 16571030116 | 11/1/2012 | 11/2/2012 | 163   | 0 | \$1,629.80   |
| HYDROCO/APAP 10-325MG TAB - 100 TAB    | 3 | 141275 | 00406036701 | 11/1/2012 | 11/2/2012 | 5,866 | 0 | \$19,064.50  |
| HYDROCO/APAP 10-500MG TAB - 100 TAB    | 3 | 118596 | 00603388821 | 11/1/2012 | 11/2/2012 | 1,896 | 0 | \$33,616.08  |
| HYDROCO/APAP 10-650 MG TAB - 100 TAB   | 3 | 118604 | 00603388521 | 11/1/2012 | 11/2/2012 | 786   | 0 | \$8,590.98   |
| HYDROCO/APAP 10-660MG TAB - 100 TAB    | 3 | 186742 | 00603388621 | 11/1/2012 | 11/2/2012 | 1,976 | 0 | \$31,517.20  |
| HYDROCO/APAP 5-325MG TAB - 100 TAB     | 3 | 144535 | 00603389021 | 11/1/2012 | 11/2/2012 | 5,237 | 0 | \$12,306.95  |
| HYDROCO/APAP 5-500MG TAB - 500 TAB     | 3 | 118612 | 00603388128 | 11/1/2012 | 11/2/2012 | 5,065 | 0 | \$113,962.50 |
| HYDROCO/APAP 7.5-325MG TAB - 100 TAB   | 3 | 186775 | 00603389121 | 11/1/2012 | 11/2/2012 | 3,956 | 0 | \$13,450.40  |
| HYDROCO/APAP 7.5-500MG TAB - 100 TAB   | 3 | 144550 | 00406035801 | 11/1/2012 | 11/2/2012 | 2,121 | 0 | \$5439.93    |
| HYDROCO/APAP 7.5-650MG TAB - 100 TAB   | 3 | 187856 | 00603388421 | 11/1/2012 | 11/2/2012 | 99    | 0 | \$856.35     |
| HYDROCOD/HOM 5-1.5MG/5ML SYP - 473 ML  | 3 | 144360 | 50383004316 | 11/1/2012 | 11/2/2012 | 1,869 | 0 | \$44,856.00  |
| HYDROCOD/IBU 7.5-200MG - 100 TAB       | 3 | 187831 | 00603389721 | 11/1/2012 | 11/2/2012 | 738   | 0 | \$2,915.10   |
| LORAZEPAM 0.5MG TAB - 500 TAB          | 4 | 118356 | 63304077205 | 11/1/2012 | 11/2/2012 | 880   | 0 | \$3,432.00   |
| LORAZEPAM 1MG TAB - 500 TAB            | 4 | 145516 | 63304077305 | 11/1/2012 | 11/2/2012 | 776   | 0 | \$3,142.72   |
| LORAZEPAM 2MG TAB - 90 TAB             | 4 | 188201 | 63304077490 | 11/1/2012 | 11/2/2012 | 595   | 0 | \$1,225.70   |
| MODAFINIL 100MG TAB - 30 TAB           | 4 | 172189 | 55253080130 | 11/1/2012 | 11/2/2012 | 87    | 0 | \$22,175.38  |
| MODAFINIL 200MG TAB - 30 TAB           | 4 | 172197 | 55253080230 | 11/1/2012 | 11/2/2012 | 604   | 0 | \$232,540.00 |
| OXAZEPAM 10MG CAP - 100 CAP            | 4 | 145292 | 00228206710 | 11/1/2012 | 11/2/2012 | 92    | 0 | \$5,611.70   |
| OXAZEPAM 15MG CAP - 100 CAP            | 4 | 144873 | 00228206910 | 11/1/2012 | 11/2/2012 | 55    | 0 | \$4,199.83   |
| PENTAZ/NAL 50-0.5MG TAB - 100 TAB      | 4 | 144972 | 00591039501 | 11/1/2012 | 11/2/2012 | 70    | 0 | \$5,186.53   |
| PHENOBARB 4MG/ML ELX - 480 ML          | 4 | 145250 | 00603150858 | 11/1/2012 | 11/2/2012 | 96    | 0 | \$918.11     |
| PHENOBARBITAL 64.8MG TAB - 100 TAB     | 4 | 187807 | 00603516721 | 11/1/2012 | 11/2/2012 | 300   | 0 | \$3,237.00   |
| PHENOBARBITAL 64.8MG TAB - 1000 TAB    | 4 | 187385 | 00603516732 | 11/1/2012 | 11/2/2012 | 53    | 0 | \$5,119.80   |
| PHENOBARBITAL 97.2MG TAB - 100 TAB     | 4 | 145326 | 00603516821 | 11/1/2012 | 11/2/2012 | 228   | 0 | \$3,475.24   |
| PHENTERMINE 30MG CAP - 100 CAP         | 4 | 145037 | 10702002701 | 11/1/2012 | 11/2/2012 | 93    | 0 | \$581.25     |
| PHENTERMINE 37.5MG TAB - 100 TAB       | 4 | 145367 | 10702002501 | 11/1/2012 | 11/2/2012 | 514   | 0 | \$1,850.34   |
| PROMETH/COD 6.25-10MG/5ML SYP - 473 ML | 5 | 187773 | 00603158558 | 11/1/2012 | 11/2/2012 | 664   | 0 | \$2,622.86   |
| TEMAZEPAM 15MG CAP - 100 CAP           | 4 | 187757 | 00378401001 | 11/1/2012 | 11/2/2012 | 836   | 0 | \$3,327.28   |
| TEMAZEPAM 30MG CAP - 100 CAP           | 4 | 187740 | 00378505001 | 11/1/2012 | 11/2/2012 | 715   | 0 | \$3,553.55   |

|                                   |   |        |             |           |           |       |   |             |
|-----------------------------------|---|--------|-------------|-----------|-----------|-------|---|-------------|
| TEMAZEPAM 7.5MG CAP - 100 CAP     | 4 | 144840 | 00406996001 | 11/1/2012 | 11/2/2012 | 60    | 0 | \$15,896.40 |
| ZALEPLON 10MG CAP - 100 CAP       | 4 | 187716 | 00093526901 | 11/1/2012 | 11/2/2012 | 100   | 0 | \$1,233.00  |
| ZALEPLON 5MG CAP - 100 CAP        | 4 | 187724 | 00093526801 | 11/1/2012 | 11/2/2012 | 46    | 0 | \$551.54    |
| ZOLPIDEM 10MG TAB - 100 TAB       | 4 | 171116 | 64679071501 | 11/1/2012 | 11/2/2012 | 3,932 | 0 | \$8,059.81  |
| ZOLPIDEM 5MG TAB - 100 TAB        | 4 | 171108 | 64679071401 | 11/1/2012 | 11/2/2012 | 1,346 | 0 | \$2,018.73  |
| ZOLPIDEM ER 12.5 MG TAB - 100 TAB | 4 | 141366 | 00955170310 | 11/1/2012 | 11/2/2012 | 491   | 0 | \$61,134.41 |
| ZOLPIDEM ER 6.25 MG TAB - 100 TAB | 4 | 244087 | 00955170210 | 11/1/2012 | 11/2/2012 | 100   | 0 | \$12,476.00 |



# INITIAL INVENTORY

NDC Audit Item Inventory Details

Registrant: HBC Service Company

DEA# RH0389773

File# \_\_\_\_\_

Page 1 of 1

Initial Inventory Date: 2/11/2013 Beginning of Business

Closing Inventory Date: 8/11/2013 Close of Business

| Inventory Date  | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
|---|-------------------|-------------------|-----------------------|-------------------|-----------------------------------|---------------------|--------------|------------------|---------------------|------------------|
| 144550 - HYDROCO/APAP 7.5-500MG TAB - 100 TAB - 00406035801 |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 2/11/2013   | 534               | 0                 | 534                   | 491               | 43                                | 0                   | 0            |                  | 534                 | 0                |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| Inventory Date  | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
| 181644 - HYDROCO/APAP 5-500MG TAB - 500 TAB - 00591034905   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 2/26/2013   | 0                 | 5,040             | 5,040                 | 5,040             | 0                                 | 0                   | 0            |                  | 5,040               | 0                |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| Inventory Date  | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
| 181297 - HYDROCO/APAP 10-325MG TAB - 100 TAB - 00603388721  |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 2/26/2013   | 0                 | 5,616             | 5,616                 | 5,616             | 0                                 | 0                   | 0            |                  | 5,616               | 0                |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| Inventory Date  | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
| 144956 - ALPRAZOLAM 2MG TAB - 100 TAB - 47335060688         |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 2/11/2013   | 194               | 0                 | 194                   | 179               | 15                                | 0                   | 0            |                  | 194                 | 0                |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| Inventory Date  | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
| 118406 - APAP/CODEIN 300/60MG TAB - 100 TAB - 00603233921   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 2/11/2013   | 162               | 0                 | 162                   | 160               | 2                                 | 0                   | 0            |                  | 162                 | 0                |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
|   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| Inventory Date  | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
| 181016 - ALPRAZOLAM ER 1MG TAB - 60 TAB - 65162081006       |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 2/27/2013   | 0                 | 120               | 120                   | 120               | 0                                 | 0                   | 0            |                  | 120                 | 0                |

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US-DEA-00030614

## NDC Audit Item Inventory Details

Page 1 of 1

Registrant: HBC Service Company

DEA# RH0389773

File# \_\_\_\_\_

Initial Inventory Date: 2/11/2013 Beginning of Business

Closing Inventory Date: 8/11/2013 Close of Business

| Inventory Date   | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
|--|-------------------|-------------------|-----------------------|-------------------|-----------------------------------|---------------------|--------------|------------------|---------------------|------------------|
| 145334 - APAP/CODEIN 120-12MG/5ML ELX - 473 ML - 00603102058 |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 2/11/2013  | 108               | 0                 | 108                   | 105               | 3                                 | 0                   | 0            |                  | 108                 | 0                |
|  |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| Inventory Date   | Initial Inventory | Received Quantity | Total Accountable For | Closing Inventory | Quantity Distributed/ Transferred | Handbilled Invoices | Adjust ments | Adjust ment Code | Total Accounted For | Total Difference |
| 182014 - CHLORDIAZEPOXIDE 10MG CAP - 100 CAP - 43547025210   |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |
| 3/28/2013  | 0                 | 132               | 132                   | 132               | 0                                 | 0                   | 0            |                  | 132                 | 0                |
|  |                   |                   |                       |                   |                                   |                     |              |                  |                     |                  |

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US-DEA-00030615

**NDC Audit Item Inventory Details**

Page 1 of 1

Registrant: HBC Service Company

DEA# RH0389773

File# \_\_\_\_\_

Initial Inventory Date: 2/11/2013 Beginning of Business

Closing Inventory Date: 8/11/2013 Close of Business

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US-DEA-00030616

**NDC Audit Item Inventory Details**

Page 1 of 1

**Registrant:** HBC Service Company

DEA# RH0389773

File#

**Initial Inventory Date:** 2/11/2013 Beginning of Business  
**Closing Inventory Date:** 8/11/2013 Close of Business

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US-DEA-00030617



U.S. Department of Justice  
Drug Enforcement Administration

REPORT OF INVESTIGATION

Page 1 of 17

|  |  |  |                                   |
|--|--|--|-----------------------------------|
| 1. Program Code  | 2. Cross File<br>Related Files   | 3. File No.<br>[REDACTED]  | 4. G-DEP Identifier<br>[REDACTED] |
| 5. By: John M Conlon, DI<br>At: Pittsburgh DO  | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | 6. File Title<br>HBC SERVICES COMPANY 601A Meadow<br>Lands BLVD WA, PA 15031 |                                   |
| 7. <input checked="" type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed<br><input type="checkbox"/> Action Requested By: |  | 8. Date Prepared<br>08-13-2013   |                                   |
| 9. Other Officers:   |  |  |                                   |
| 10. Report Re: Case Closing and Cyclic Investigation of HBC Service Company, 601 A Meadowland<br>Blvd., Washington, PA DEA # RH0389773 [REDACTED]  |  |  |                                   |

**SYNOPSIS**

On August 12, 2013, pursuant to the Pittsburgh District Office cyclic workplan for FY 2013, Investigators John Conlon and Jeff Sousa conducted an on-site regulatory investigation of HBC SERVICES COMPANY, INC., a Division of GIANT EAGLE, INC., located at 601 A Meadowlands Boulevard, Washington, PA 15301.

HBC SERVICE COMPANY, INC. is registered with DEA as a distributor, under DEA registration number RH0389773 to handle controlled substances in schedules 3, 3N, 4 and 5. This registration expires on October 31, 2014. The on site portion of this investigation began on August 12, 2013 and concluded on August 13, 2013.

This investigation revealed no discrepancies with respect to recordkeeping or security. Therefore, this case is closed.

|                               |   |                        |
|-------------------------------|---|------------------------|
| 11. Distribution:<br>Division | 12. Signature (Agent)<br>John M Conlon, DI              | 13. Date<br>08-14-2013 |
| District                      | 14. Approved (Name and Title)<br>/s/ Kurt G Dittmer, GS | 15. Date<br>08-27-2013 |
| Other [REDACTED]              |   |                        |

DEA Form - 6  
(Jul. 1996)

DEA SENSITIVE  
Drug Enforcement Administration

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Previous edition dated 8/94 may be used.

U.S. Department of Justice  
Drug Enforcement Administration

|   |  |                                   |
|---|--|-----------------------------------|
| <b>REPORT OF INVESTIGATION</b><br><i>(Continuation)</i> | 1. File No.<br>[REDACTED]  | 2. G-DEP Identifier<br>[REDACTED] |
|   | 3. File Title<br>HBC SERVICES COMPANY 601A Meadow<br>Lands BLVD WA, PA 15031 |                                   |
| 4.<br>Page 2 of 17                                      |  |                                   |
| 5. Program Code   | 6. Date Prepared<br>08-13-2013   |                                   |

**ENCLOSURES**

1. DEA-82 - Notice of Inspection
2. PA Dept of Health Drug Distributorship Certificate
3. West VA Pharmacy Drug Distributorship Permit
4. State of Ohio Pharmacy Drug Distributorship Certificate
5. Audit Computation Chart
6. DEA Biennial Inventory
7. Initial Inventory
8. HBC NDC Audit Sheets and Sample Detail Reports
9. HBC sample purchase records
10. List of persons with access to controlled substances
11. Sample Inventory Adjustment Form

DEA Form - 6a  
(Jul. 1996)

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U.S. Department of Justice  
Drug Enforcement Administration

|   |  |                                   |
|---|--|-----------------------------------|
| <b>REPORT OF INVESTIGATION</b><br><i>(Continuation)</i> | 1. File No.<br>[REDACTED]  | 2. G-DEP Identifier<br>[REDACTED] |
|   | 3. File Title<br>HBC SERVICES COMPANY 601A Meadow<br>Lands BLVD WA, PA 15031 |                                   |
| 4.<br>Page 3 of 17                                      |  |                                   |
| 5. Program Code   | 6. Date Prepared<br>08-13-2013   |                                   |

**DETAILS**

**1. BASIS OF INVESTIGATION**

On August 12, 2013, pursuant to the Pittsburgh District Office cyclic workplan for FY 2013, Investigators John Conlon and Jeff Sousa conducted an on-site regulatory investigation of HBC SERVICES COMPANY, INC., a Division of GIANT EAGLE, INC., located at 601 A Meadowlands Boulevard, Washington, PA 15301, telephone number 724-8703-5100.

HBC SERVICE COMPANY is registered with DEA as a distributor under DEA# RH0389773 to distribute Schedule III thru V controlled substances. This registration expires on October 31, 2013. This investigation was initiated on August 12, 2013, and concluded on August 13, 2013 with a meeting with management.

**2. SUBJECT FIRM'S BACKGROUND**

HBC (Health and Beauty Care) SERVICE COMPANY, located at 601 A Meadowlands Boulevard, Washington, PA, 15301, is a division of GIANT EAGLE, INC., with corporate headquarters at 101 Kappa Drive, Pittsburgh, PA, 15238. The subject firm distributes general merchandise, health and beauty aids, over-the-counter products containing List I chemicals, and Scheduled III - V controlled substances to approximately 220 Giant Eagle supermarkets located in Pennsylvania, West Virginia, and Ohio. Giant Eagle pharmacies are the subject firm's sole customer base. HBC SERVICE COMPANY had \$157,000,000 dollars in sales during 2012, of which controlled substances accounted for less than one percent.

HBC SERVICE COMPANY, hereinafter referred to as HBC, was approved as a drug distributor in 2009 and issued DEA registration number RH0389773 under DEA file number [REDACTED]. This registration expires on October 31, 2013. HBC was the subject of its first regulatory inspection/cyclic investigation in May 2011, and documented under DEA file number [REDACTED]. The result of this investigation revealed minor recordkeeping violations (an overage due to computer software malfunction).

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HBC is also registered with DEA as a distributor of List I chemicals under DEA Registration Number 001753HVY. The subject firm was the subject of in-depth chemical regulatory/cyclic investigations in 2002 [REDACTED], 2004 [REDACTED], and 2008 [REDACTED]. No violations were uncovered during these investigations.

HBC is licensed with the Commonwealth of Pennsylvania, Department of Health, as a distributor of prescription medicine, Certificate Number 3000008128, which expires on March 31, 2014 (ENCLOSURE #2). HBC is licensed with the State of West Virginia, Board of Pharmacy as a wholesale drug distributor under license number WD0558704, which expires on June 30, 2014 (ENCLOSURE #3). HBC is licensed with the State of Ohio, Board of Pharmacy as a distributor of controlled substances under ID Number WCSW 2458 0464. This registration expires on June 30, 2014 (ENCLOSURE #4).

### 3. PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

On August 12, 2013, Investigators Conlon and Sousa presented their credentials and a Notice of Inspection (DEA Form 82) (ENCLOSURE #1) to Matt ROGOS, HBC Distribution Operations Manager, for the subject firm. ROGOS then read and signed the DEA Form 82, giving his consent for the inspection to proceed. ROGOS stated that he is responsible for the subject firm's operations, with respect to controlled substances and List I chemicals. ROGOS and Christy HART, HBC Senior Coordinator Pharmacy Operations, provided all the necessary records and information required to conduct this investigation.

### 4. PRINCIPALS OF THE FIRM

Lora Karet, President and COO  
Larry Baldauf, Senior VP of Distribution  
Robert Schreck, VP of Distribution  
Matthew Rogos, Distribution Operations Manager

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NADDIS queries on these individuals did not reveal any negative information.

## 5. SCOPE OF INVESTIGATION

The on-site portion of the investigation commenced on August 12, 2013, and concluded on August 13, 2013, with a meeting with management.

An accountability of hydrocodone 5mg. tablets (500 count bottles), hydrocodone 7.5mg. tablets (100 count bottles), hydrocodone 10mg. tablets (100 count bottles), acetaminophen with codeine 60mg. tablets (100 count bottles), alprazolam 1mg. tablets (60 count bottles), alprazolam 2mg. tablets (100 count bottles), chlorthalidone 10mg. tablets (100 count bottles), and apap. with codeine 12mg/5ml elixir (734 ml bottles) was conducted for the period February 11, 2013 (BOB), through August 12, 2013 (COB).

The results of this audit are listed below and documented on the attached computation chart (ENCLOSURE #5). This accountability audit revealed no discrepancies. (All figures are in dosage units)

| <u>Drug</u>                | <u>Init.</u><br><u>Inv.</u> | <u>Purch.</u> | <u>Total</u> | <u>Clos.</u><br><u>Inv.</u> | <u>Sales</u> | <u>Total</u> | <u>%</u> |
|----------------------------|-----------------------------|---------------|--------------|-----------------------------|--------------|--------------|----------|
| Hydrocod<br>0<br>5mg.      | 0                           | 5,706,000     | 5,706,000    | 846,000                     | 4,860,000    | 5,706,000    |          |
| Hydrocod<br>200 0<br>7.5mg | 53,400                      | 556,800       | 610,200      | 41,100                      | 569,100      | 610,         |          |
| Hydrocod<br>0<br>10mg.     | 0                           | 1,826,400     | 1,826,400    | 257,200                     | 1,569,200    | 1,826,400    |          |

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|                                   |        |         |         |        |         |         |
|-----------------------------------|--------|---------|---------|--------|---------|---------|
| Alprazolol<br>0<br>1mg.           | 0      | 7,200   | 7,200   | 1,620  | 5,580   | 7,200   |
| Alprazolol<br>0<br>2mg.           | 19,400 | 249,600 | 269,000 | 41,700 | 227,300 | 269,000 |
| Apap/Codolone<br>0<br>60mg        | 16,200 | 98,400  | 114,600 | 14,600 | 100,000 | 114,600 |
| Chlordiazepoxide<br>0<br>10mg.    | 0      | 39,600  | 39,600  | 9,700  | 29,900  | 39,600  |
| Codeine<br>0<br>elix.12mg/<br>5ml | 79,272 | 343,512 | 422,784 | 46,242 | 376,542 | 422,784 |

## 6. RECORDKEEPING

### Biennial Inventory:

A biennial inventory, as required by Title 21 C.F.R. 1304.11 (c), was taken by the subject firm on Nov. 1, 2012. (ENCLOSURE #6)

### Initial Inventory:

The figures for the initial inventory portion of the audit were taken from the firm's "NDC Audit Item Inventory" report dated Feb. 11, 2013. Among other internal data, this computer-generated report captures the date, drug name, strength, bottle size, and quantity on hand for each controlled substance. ROGOS provided these figures as factual for the

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purposes of the audit's initial inventory. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

#### **Closing Inventory:**

On August 12, 2013, DIs Conlon and Sousa conducted a physical count, closing inventory, which was witnessed by ROGOS. This physical count was compared against the subject firm's "Item Inquiry" report which is a daily control substance inventory report, sorted by item number associated with each separate controlled substance. Among other internal data, this computer-generated report captures the date, time, drug name, strength, bottle size, and quantity on hand for each controlled substance. These figures were compared against the actual physical count and no discrepancies were found. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

#### **Receiving/Purchasing Records:**

The subject firm's purchase records are documented via the the original purchase invoices from the drug suppliers, which are physically maintained and entered into a computer database by drug item number. These figures are captured on the subject firm's "NDC Audit Item Inventory Detail" report, a computer-generated report which, among other internal data, captures a complete, daily perpetual inventory of purchases and distributions of a particular controlled substance by date range (ENCLOSURE #9). A random selection of several purchases were taken from the "NDC Audit Item Inventory Detail" report, and compared against the original source document/purchase invoices for accuracy. No discrepancies were noted. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b). It should be noted that although the subject firm's drug distribution warehouse has computerized access to the "NDC Audit Item Inventory Detail" report, in order to compare this report against the original source document/purchase invoices, the investigators had to travel to the subject firm's corporate headquarters located at the RIDC Industrial Park, 101 Kappa Drive, Bldg. III, Pittsburgh, PA 15238. All purchases are a function of a centralized purchasing unit base at the subject firm's corporate headquarters. On August 13, 2013, Investigators met with Asst. Purchasing Mgr. Kris Remas to review

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purchasing records. No discrepancies were found. It should be noted that the subject firm submitted a written request for authorization for central recordkeeping for the purchase records to be physically stored at its corporate headquarters during the cyclic investigation conducted in 2011 under file number [REDACTED]

**Sales/Distribution Records:**

Since HBC is a division of Giant Eagle Supermarkets, its sole customer base is 220 Giant Eagle pharmacies located throughout PA, W.VA, and OH. Sales are initiated at the store level and are computer-generated from the individual store and transmitted to the subject firm on a daily basis. These computer-generated invoices capture information such as pharmacy location, DEA number, date of distribution, drug, strength and quantity sold (ENCLOSURE #8). These distribution transactions are captured on the subject firm's "Item Invoice Report" which documents daily distributions, within a specified date range, of each particular controlled substance to all customers. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).

**DAMAGED/RETURNED ITEMS:**

There were no returned items noted during the audit period. The subject firm utilizes Capital Returns as its reverse distributor in order to destroy controlled substances. There were no destructions of controlled substances noted during the audit period. There were 24 damaged bottles of hydrocodone 5mg. (500 bottle count) that were segregated and secured within the Schedule III through V drug cage, which were awaiting destruction. The damage to these bottles was documented via internal emails, and subsequently recorded on a computerized variance report entitled "Pharmacy Warehouse Inventory Adjustments" report. These 24 bottles were factored into the above audit. No discrepancies were found (ENCLOSURE #11).

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7. **ARCOS**

Prior to conducting the onsite inspection, Investigator Conlon requested an ARCOS print out from Program Analyst June Howard of the ARCOS Unit at DEA HQ, ADS /ODPT, of the pre-selected controlled substances to be audited. Kris REMAS, of the subject firm's corporate headquarters, advised that she is responsible for reporting to ARCOS on a quarterly basis. ARCOS reports are current. However, there was an ARCOS Error Report which indicated there were XX of errors of NDC codes reported. REMAS was made aware of these errors and advised that she would research the correct NDC codes and transmit a corrected report to ARCOS. The information contained in ARCOS was utilized to verify purchase information supplied by the subject firm during the audit period. No discrepancies were noted.

8. **SECURITY**

HBC SERVICE COMPANY is the sole occupant of a 305,000 square foot warehouse, constructed of steel reinforced poured concrete, concrete block, and steel. This warehouse is located within the Meadowlands Industrial Park, a light industrial park in rural Washington County, PA. A sign at the entrance to the property identifies the tenant as HBC Service Company. There is no signage that would indicate the presence of a company involved in the distribution of controlled substances or List I chemicals. The firm operates six days per week, 24 hours per day, in three 8-hour shifts. There are approximately 250 warehouse employees working varied hours. Of these personnel, only twelve people have routine access to controlled substances, and an additional forty-five persons have routine access to non-controlled pharmaceutical drugs and List I chemicals.

A visual inspection of the facility revealed strategically-placed passive infrared motion detectors throughout the entire facility. All external doors and internal doors leading to the warehouse are substantially-constructed steel fire doors. All external doors possess balanced magnetic contact alarm switches. All internal/external warehouse doors are accessed via electromagnetic locks, which are activated via a key fob device. These devices are programmed to allow access to only authorized

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persons to secure areas of the warehouse. In addition, these devices allow the subject firm to identify the date and time of employee ingress and egress to the warehouse and secured portions of the warehouse.

The main visitors entrance is protected by a double set of steel reinforced glass double doors. Once a visitor gains entrance into the vestibule area, a receptionist screens all visitors and then releases an electromagnetic lock allowing entrance into the administrative office section of the facility. All visitors are identified and must sign a visitors log. No visitors are left unescorted.

Glass break sensors are located in all rooms with exterior windows. There are forty strategically placed surveillance cameras that are positioned both inside and outside the warehouse facility. These cameras surveil the parking lot, the employee entrance, shipping and receiving doors, and all areas of the warehouse. The video surveillance is stored on site for a period of 30 days, and is archived for a longer period of time at corporate headquarters. The exterior of the warehouse is illuminated from dusk to dawn by industrial grade security lighting.

All controlled substances are stored in a steel cage measuring approximately 30' width x 40' depth x 22' height. The walls and ceiling of the cage, along with cage doors, are constructed of #10 gauge steel mesh fabric. There is one man door, one forklift gate, and one small tote-sized access door to the cage. Each is equipped with a balanced magnetic contact alarm switch and lock. The cage is also equipped with four strategically-placed passive infrared motion detectors. There are also three video surveillance cameras located within the Schedule III through V controlled substance cage. The cage possesses an independently-zoned alarm keypad to activate and deactivate the cage alarm independently from the rest of the warehouse. All elements of this cage meet the requirements specified in 21 CFR 1301.72(b)(4).

The Schedule III through V controlled substances security cage is located in a secure and segregated portion of the warehouse, known as the pharmacy section. This secure and segregated section of the warehouse occupies 12,00 square feet. In addition to the three security cameras located within the controlled substance cage, there are sixteen security cameras

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located within the entire pharmacy section, and an additional four security cameras monitor the exterior perimeter of the pharmacy room. This portion of the warehouse also possesses an independently-zoned alarm keypad to activate and deactivate an alarm independently from the rest of the warehouse.

All HBC team members with access to the cage or those involved in handling the controlled substances undergo required background checks. ROGOS advised that before an employee is hired, a criminal history background check is conducted. He stated that the firm has a "zero tolerance" policy with respect to employee pilferage, which means that an employee caught stealing merchandise is immediately terminated from employment. According to the information provided by ROGOS, the employee screening process and associated security measures are in compliance with the regulations set forth in Title 21 CFR Parts: 1301.76, 1301.90, 1301.92 and 1301.93.

The firm's electronic security is monitored by Sonotrol Security Company. ROGOS advised the investigators that when an alarm sensor is activated in the firm, a signal is transmitted to Sonotrol, who then notifies the South Strabane Township Police Department, located less than five minutes from the firm. After the police department is notified, Sonotrol will call a representative from the subject firm. According to ROGOS, the firm has not had any break-ins or robberies. When an alarm is activated, an audible alarm can be heard throughout the warehouse.

ROGOS stated that, in the event of a power outage, the firm's electronic security is maintained through a battery backup system.

The cage inside the pharmacy room that contains the controlled substances remains locked at all times when not in use. It is permissible for the cage to be unlocked when in use as long as it is being monitored by the coordinator or a member of the management team. Keys to unlock the cage and the alarm activation/deactivation codes are in possession of the HBC operation's management team only.

Prior to a delivery truck arriving or departing from the warehouse facility, exterior mounted video surveillance cameras are viewed at a terminal located in the pharmacy warehouse to ensure there are no unknown

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persons or vehicles near the facilities loading docks. When a delivery truck is backed into the loading dock platform there is a security device that shrouds the rear of the truck making it impossible to gain access to the pharmacy warehouse room from the building's exterior. Once the vehicle is locked in place, the supervisor closes the exterior door before allowing the driver to enter. The supervisor ensures the holding area is secure and then allows the driver into the holding area. Once the exterior door is closed behind the driver, the supervisor will release the holding area door to allow the driver inside the pharmacy warehouse.

The supervisor will then unlock the padlock that secures the grade-level garage door. If the delivery contains controlled substances, the supervisor unlocks the cage so the product can be taken directly into the protected area. The reconciliation takes place inside the cage by the receiver, but excludes the driver. If the driver arrives for pick up, the supervisor follows the same steps indicated for the receiving process before allowing the driver access inside.

On August 12, 2013, investigators tested all aspects of the firm's electronic security. The security was operational and deemed adequate.

ROGOS informed DIs Conlon and Sousa that the following individuals have routine access to HBC's controlled substance storage cage (ENCLOSURE #10):

| NAME               | SSN        | DOB        |
|--------------------|------------|------------|
| Jeff Biddle        | [REDACTED] | [REDACTED] |
| William Cudipp     |            |            |
| William Hevia      |            |            |
| Steven Post        |            |            |
| Matt Rogos         |            |            |
| Stephannie Summers |            |            |
| Justin Baer        |            |            |
| Brain Becquet      |            |            |
| Christy Hart       |            |            |
| Richard Poland III |            |            |
| John Vinski        |            |            |
| Becky Walton       |            |            |

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A NADDIS check revealed no derogatory information on these individuals. There is a pool of 45 additional employees who have access to the non-controlled pharmaceutical drugs contained in the pharmacy warehouse, located outside of the Schedule III through V controlled substance cage. These employees undergo the same background checks and have the same level of security as those individual who have access to the controlled substances. When the need arises, on a short term basis, such as an unscheduled illness, a temporary replacement employee maybe transferred from non-controlled drugs to controlled drugs.

#### 9. DUE DILIGENCE

HBC Operations Manager Matt ROGOS advised the investigators that, unlike other drug distributorships, HBC has only one customer, Giant Eagle Pharmacies. All orders for controlled substances are made via dedicated Giant Eagle pharmacy computer systems, whereby only pharmacists can place electronic orders for Schedule III through V controlled substances. ROGOS advised that, at the store level, the pharmacist placing the order may not be the pharmacist on duty when the order is received. When orders are received at the pharmacy, it is the responsibility of a pharmacist and a pharmacy technician to enter controlled substances into the pharmacy inventory. DI Conlon provided ROGOS with the cite from Title 21 CFR section 1301.74(b) which states, "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from normal patterns and orders of unusual frequency." ROGOS advised, at this time, HBC and/or Giant Eagle, Inc., its parent company, has no computerized software system to indicate that an order may be suspicious. ROGOS advised that if a Giant Eagle pharmacy were to receive unusually high orders of controlled substances from HBC, deviating from other stores, it would be noticed at the Giant Eagle, Inc. headquarters level. ROGOS stated that he will bring this issue to the attention of Greg CARLSON and Kim REMAS of Giant Eagle's headquarters Controlled Substance Purchasing Unit.

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#### 10. MEETING WITH MANAGEMENT

On August 13, 2013, Diversion Investigators Conlon and Sousa meet with HBC Operations Manager Matt ROGOS to discuss the results of the audit. During this meeting, investigators advised ROGOS that both recordkeeping and security are in full compliance with the requirements set forth in Title 21 Code of Federal Regulations. Investigator Conlon advised ROGOS to develop a better system of due diligence.

#### 11. VERIFICATIONS

On August 15, 2013, the Giant Eagle Pharmacy located in Kennedy Township was contacted to verify an order shipped by HBC SERVICE COMPANY, on July 24, 2013. The pharmacist on duty confirmed the purchase of controlled substances from the HBC SERVICE COMPANY.

On August 15, 2013, the Giant Eagle Pharmacy located in Robinson Township was contacted to verify an order shipped by HBC SERVICE COMPANY, on July 24, 2013. The pharmacist on duty confirmed the purchase of controlled substances from the HBC SERVICE COMPANY.

ARCOS records were utilized to verify purchases of controlled substances by HBC SERVICE COMPANY.

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**INDEXING**

1. HBC SERVICE COMPANY [REDACTED]  
\*\*\* ( 08/2013 [REDACTED] ) Regulatory investigation, no violations.

2. ROGOS, Matthew [REDACTED]  
[REDACTED]  
\*\*\* ( 08/2013 re: [REDACTED] ) Employed as OPS. MGR. for HBC (DEA # RH0389773). Access to controlled substances.

3. BIDDLE, Jeff [REDACTED]  
[REDACTED]  
\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

4. CUDIPP, William [REDACTED]  
[REDACTED]  
\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

5. HEVIA, William [REDACTED]  
[REDACTED]  
\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

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6. POST, Steven [REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

7. SUMMERS, Stephannie [REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

8. BAER, Justin [REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

9. BECQUET, Brian [REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

10. HART, Christy [REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

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11. POLAND, Richard, III  
[REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

12. VINSKI, John  
[REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

13. WALTON, Becky  
[REDACTED]

\*\*\* ( 08/2013 re: [REDACTED] ) Employed by HBC (DEA # RH0389773). Access to controlled substances.

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|--|--------------------------------|--|-----------------------------------|
| 1. Program Code  | 2. Cross File<br>Related Files | 3. File No.<br>[REDACTED]  | 4. G-DEP Identifier<br>[REDACTED] |
| 5. By: Jeffrey S Sousa, DI<br>At: Pittsburgh DO  | [REDACTED]                     | 6. File Title<br>HBC SERVICE CO, 601A Meadowlands<br>Blvd Washington, PA |                                   |
| 7. <input checked="" type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed<br><input type="checkbox"/> Action Requested By: |                                | 8. Date Prepared<br>12-03-2014   |                                   |
| 9. Other Officers: DI John Conlon  |                                |  |                                   |
| 10. Report Re: Case Closing (Scheduled Investigation) of HBC SERVICES CO, 601A Meadowlands<br>Blvd, Washington, PA 15031 DEA #RH0389773 [REDACTED] |                                |  |                                   |

**SYNOPSIS**

On December 2, 2014, pursuant to the Pittsburgh District Office (PGH DO) cyclic workplan for FY 2015, Diversion Investigators (DI) Jeffrey Sousa and John Conlon conducted an on-site regulatory investigation of HBC SERVICES COMPANY, INC., a Division of GIANT EAGLE, INC., located at 601 A Meadowlands Boulevard, Washington, PA 15301.

HBC SERVICE COMPANY, INC. (HBC) (DEA # RH0389773, expiration October 31, 2015, NADDIS [REDACTED]) is registered with DEA as a distributor to handle controlled substances in schedules 3, 3N, 4 and 5. The onsite portion of this investigation began and concluded on December 2, 2014.

This investigation revealed no discrepancies with respect to recordkeeping or security. The audit of controlled substances revealed no overages or shortages.

No further action is required. This case is closed.

|                               |   |                        |
|-------------------------------|---|------------------------|
| 11. Distribution:<br>Division | 12. Signature (Agent)<br>Jeffrey S. Sousa, DI       | 13. Date<br>12-02-2014 |
| District                      | 14. Approved (Name and Title)<br>Kurt G Dittmer, GS | 15. Date<br>12/11/2014 |
| Other [REDACTED]              |   |                        |

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**ENCLOSURES**

1. DEA-82 - Notice of Inspection
2. PA Dept of Health Drug Distributorship/ Wholesaler Certificates (2pgs)
3. West VA Pharmacy Controlled Substance/ Drug Distributorship Permit (2pgs)
4. State of Ohio Pharmacy Drug Distributorship Certificates (2pgs)
5. DEA Biennial Inventory (2pgs)
6. Closing Inventory
7. Audit Computation Chart
8. HBC NDC Audit Sheets and Sample Detail Reports (77pgs)
9. HBC sample purchase records (14pgs)

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**DETAILS**

**1. BASIS OF INVESTIGATION**

On December 2, 2014, pursuant to the Pittsburgh District Office (PGH DO) cyclic workplan for FY 2015, Diversion Investigators (DI) Jeffrey Sousa and John Conlon conducted an on-site regulatory investigation of HBC SERVICES COMPANY, INC., a Division of GIANT EAGLE, INC., located at 601 A Meadowlands Boulevard, Washington, PA 15301.

HBC SERVICE COMPANY, INC. (HBC) (DEA # RH0389773, expiration October 31, 2015, NADDIS [REDACTED]) is registered with DEA as a distributor to handle controlled substances in schedules 3, 3N, 4 and 5. The onsite portion of this investigation began and concluded on December 2, 2014. This investigation was initiated on August 12, 2013, and concluded on December 2, 2014, with a meeting with management.

**2. SUBJECT FIRM'S BACKGROUND**

HBC (Health and Beauty Care) SERVICE COMPANY, located at 601 A Meadowlands Boulevard, Washington, PA, 15301, is a division of GIANT EAGLE, INC., with corporate headquarters at 101 Kappa Drive, Pittsburgh, PA, 15238. The subject firm distributes general merchandise, health and beauty aids, over-the-counter products containing List I chemicals, and Scheduled III - V controlled substances to approximately 220 Giant Eagle supermarkets located in Pennsylvania, West Virginia, and Ohio. Giant Eagle pharmacies are the subject firm's sole customer base. HBC SERVICE COMPANY had \$157,000,000 dollars in sales during 2014, of which controlled substances accounted for less than one percent.

HBC was approved as a drug distributor in 2009 and issued DEA registration number RH0389773 under DEA file number [REDACTED]. This registration expires on October 31, 2015. HBC was the subject of its first regulatory inspection/cyclic investigation in May 2011, and documented under DEA file number [REDACTED]. The result of this investigation revealed minor recordkeeping violations (an overage due to computer software malfunction). HBC was the subject of regulatory /cyclic investigation in

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August 2013, under file number [REDACTED] resulting in no discrepancies or violations uncovered.

HBC is also registered with DEA as a distributor of List I chemicals under DEA Registration Number 001753HVV. The subject firm was the subject of in-depth chemical regulatory/cyclic investigations in 2002 [REDACTED] 2004 [REDACTED], 2008 [REDACTED], and 2014 [REDACTED] No violations were uncovered during these investigations.

HBC is licensed with the Commonwealth of Pennsylvania, Department of Health, as a distributor of prescription medicine, Certificate Number 3000008128, which expires on March 31, 2015 (ENCLOSURE #2). HBC is licensed with the State of West Virginia, Board of Pharmacy as a wholesale drug distributor under license number WD0558704, which expires on June 30, 2015 (ENCLOSURE #3). HBC is licensed with the State of Ohio, Board of Pharmacy as a distributor of controlled substances under ID Number WCSW 2458 0464. This registration expires on June 30, 2015 (ENCLOSURE #4).

### 3. PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

On December 2, 2014, Investigators Sousa and Conlon presented their credentials and a Notice of Inspection (DEA Form 82) (ENCLOSURE #1) to Robert KUTCHA, HBC Inventory Manager, for the subject firm. KUTCHA read and signed the DEA Form 82, giving his consent for the inspection to proceed. KUTCHA stated that he is responsible for the subject firm's inventory operations, with respect to controlled substances and List I chemicals. Matt ROGOS, Operations Manager, KUTCHA and Christy HART, HBC Senior Coordinator Pharmacy Operations, provided all the necessary records and information required to conduct this investigation.

### 4. PRINCIPALS OF THE FIRM

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Lora Karet, President and COO

Joe Hurley, Senior VP of Distribution

Carmen Ford, VP of Distribution

Matthew Rogos, Distribution Operations Manager

**INVESTIGATIVE NOTE:** Larry Balduf (Senior VP of Distribution) and Robert Schreck (VP of Distribution) retired from HBC in 2012.

NADDIS queries on these individuals did not reveal any negative information.

#### 5. SCOPE OF INVESTIGATION

The on-site portion of the investigation commenced on December 2, 2014, and concluded on December 2, 2014, with a meeting with management.

An accountability of Butalbital (Schedule IIIN, drug code 2100) Zopiclone (Eszopiclone) (Schedule IV, drug code 2784) 1mg tab and 2mg tab, Flurazepam (Schedule IV, drug code 2767) 15mg and 30mg cap, and Lorazepam (Schedule IV, drug code 2885) 1mg tab, was conducted for the period June 30, 2014 (BOB), through December 1, 2014 (COB).

The results of this audit are listed below and documented on the attached computation chart (ENCLOSURE #7). This accountability audit revealed no discrepancies. (All figures are in number of bottles/containers)

HBC SERVICES

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Initial Inventory BOB 6/30/2014  
Date:  
Closing Inventory COB 12/1/2014  
Date: DATE 12/2/2014

| Drug Name, Strength, Form | Initial Inventory | Received | Total Accountable For | Closing Inventory | Distributed / Transferred | Total Accounted For | Total Difference | % Difference |
|---------------------------|-------------------|----------|-----------------------|-------------------|---------------------------|---------------------|------------------|--------------|
| Butabital/asp/caf cap     | 89                | 576      | 665                   | 106               | 559                       | 665                 | 0                | 0.00%        |
| Eszopiclone 1mg tab       | 20                | 192      | 212                   | 40                | 172                       | 212                 | 0                | 0.00%        |
| Eszopiclone 2mg tab       | 125               | 288      | 413                   | 64                | 349                       | 413                 | 0                | 0.00%        |
| Flurazepam 15mg cap       | 19                | 72       | 91                    | 15                | 76                        | 91                  | 0                | 0.00%        |
| Flurazepam 30mg cap       | 17                | 24       | 41                    | 13                | 28                        | 41                  | 0                | 0.00%        |
| Lorazepam 1mg tab         | 291               | 1,584    | 1,875                 | 296               | 1579                      | 1,875               | 0                | 0.00%        |

## 6. RECORDKEEPING

### Biennial Inventory:

A biennial inventory, as required by Title 21 C.F.R. 1304.11 (c), was taken by the subject firm on Nov. 1, 2014. (ENCLOSURE #5)

### Initial Inventory:

The figures for the initial inventory portion of the audit were taken from the firm's "NDC Audit Item Inventory" report dated June 30, 2014. Among other internal data, this computer-generated report captures the date, drug name, strength, bottle size, and quantity on hand for each controlled substance. ROGOS provided these figures as factual for the purposes of the audit's initial inventory. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

### Closing Inventory:

On December 2, 2014, DIs Sousa and Conlon conducted a physical count, closing inventory, which was witnessed by HART. This physical count was

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compared against the subject firm's "Item Inquiry" report which is a daily control substance inventory report, sorted by item number associated with each separate controlled substance. Among other internal data, this computer-generated report captures the date, time, drug name, strength, bottle size, and quantity on hand for each controlled substance. These figures were compared against the actual physical count and no discrepancies were found. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

**Receiving/Purchasing Records:**

The subject firm's purchase records are documented via the original purchase invoices from the drug suppliers, which are physically maintained and entered into a computer database by drug item number. These figures are captured on the subject firm's "NDC Audit Item Inventory Detail" report, a computer-generated report which, among other internal data, captures a complete, daily perpetual inventory of purchases and distributions of a particular controlled substance by date range (ENCLOSURE #9).

A random selection of several purchases were taken from the "NDC Audit Item Inventory Detail" report, and compared against the original source document/purchase invoices for accuracy. No discrepancies were noted. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).

**INVESTIGATIVE NOTE:** It should be noted that although the subject firm's drug distribution warehouse has computerized access to the "NDC Audit Item Inventory Detail" report, in order to compare this report against the original source document/purchase invoices, the investigators had to travel to the subject firm's corporate headquarters located at the RIDC Industrial Park, 101 Kappa Drive, Bldg. III, Pittsburgh, PA 15238. All purchases are a function of a centralized purchasing unit base at the subject firm's corporate headquarters.

On December 2, 2014, the investigators reviewed these records with HART. No discrepancies were found.

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**INVESTIGATIVE NOTE:** It should be noted that the subject firm submitted a written request for authorization for central recordkeeping for the purchase records to be physically stored at its corporate headquarters during the cyclic investigation conducted in 2011 under file number [REDACTED]

**Sales/Distribution Records:**

Since HBC is a division of Giant Eagle Supermarkets, its sole customer base is 220 Giant Eagle pharmacies located throughout PA, W.VA, and OH. Sales are initiated at the store level and are computer-generated from the individual store and transmitted to the subject firm on a daily basis. These computer-generated invoices capture information such as pharmacy location, DEA number, date of distribution, drug, strength and quantity sold (ENCLOSURE #8). These distribution transactions are captured on the subject firm's "Item Invoice Report" which documents daily distributions, within a specified date range, of each particular controlled substance to all customers. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).

**Damaged/Returned Items:**

There were no returned items noted during the audit period. The subject firm utilizes Capital Returns as its reverse distributor in order to destroy controlled substances. There were no destructions of controlled substances noted during the audit period.

**7. ARCOS**

Prior to conducting the onsite inspection, DI Sousa reviewed an ARCOS print out of the pre-selected controlled substances to be audited. ARCOS reports are current. However, there were was an ARCOS Error Report which indicated there were 490 lines of errors of NDC codes reported. DI Sousa telephoned Jim Cornwell, Giant Eagle Purchasing Manager, and advised him of these errors. Cornwell stated that he would research the correct NDC codes and transmit a corrected report to ARCOS. The information contained in ARCOS was utilized to verify purchase information supplied by the subject firm during the audit period. No discrepancies were noted.

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## 8. SECURITY

HBC SERVICE COMPANY is the sole occupant of a 305,000 square foot warehouse, constructed of steel reinforced poured concrete, concrete block, and steel. This warehouse is located within the Meadowlands Industrial Park, a light industrial park in rural Washington County, PA. A sign at the entrance to the property identifies the tenant as HBC Service Company. There is no signage that would indicate the presence of a company involved in the distribution of controlled substances or List I chemicals. The subject firm operates six days per week, 24 hours per day, in three 8-hour shifts. There are approximately 250 warehouse employees working varied hours. Of these personnel, only twelve people have routine access to controlled substances, and an additional forty-five persons have routine access to non-controlled pharmaceutical drugs and List I chemicals.

A visual inspection of the facility revealed strategically-placed passive infrared motion detectors throughout the entire facility. All external doors and internal doors leading to the warehouse are substantially-constructed steel fire doors. All external doors possess balanced magnetic contact alarm switches. All internal/external warehouse doors are accessed via electromagnetic locks, which are activated via a key fob device. These devices are programmed to allow access to only authorized persons to secure areas of the warehouse. In addition, these devices allow the subject firm to identify the date and time of employee ingress and egress to the warehouse and secured portions of the warehouse.

The main visitor's entrance is protected by a double set of steel reinforced glass double doors. Once a visitor gains entrance into the vestibule area, a receptionist screens all visitors and then releases an electromagnetic lock allowing entrance into the administrative office section of the facility. All visitors are identified and must sign a visitor's log. No visitors are left unescorted.

Glass break sensors are located in all rooms with exterior windows. There are forty strategically placed surveillance cameras that are positioned both inside and outside the warehouse facility. These cameras surveil the

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parking lot, the employee entrance, shipping and receiving doors, and all areas of the warehouse. The video surveillance is stored on site for a period of 30 days, and is archived for a longer period of time at corporate headquarters. The exterior of the warehouse is illuminated from dusk to dawn by industrial grade security lighting.

All controlled substances are stored in a steel cage measuring approximately 30' width x 40' depth x 22' height. The walls and ceiling of the cage, along with cage doors, are constructed of #10 gauge steel mesh fabric. There is one man door, one forklift gate, and one small tote-sized access door to the cage. Each is equipped with a balanced magnetic contact alarm switch and lock. The cage is also equipped with four strategically-placed passive infrared motion detectors. There are also three video surveillance cameras located within the Schedule III through V controlled substance cage. The cage possesses an independently-zoned alarm keypad to activate and deactivate the cage alarm independently from the rest of the warehouse. All elements of this cage meet the requirements specified in 21 CFR 1301.72(b)(4).

The Schedule III through V controlled substances security cage is located in a secure and segregated portion of the warehouse, known as the pharmacy section. This secure and segregated section of the warehouse occupies 12,000 square feet. In addition to the three security cameras located within the controlled substance cage, there are sixteen security cameras located within the entire pharmacy section, and an additional four security cameras monitor the exterior perimeter of the pharmacy room. This portion of the warehouse also possesses an independently-zoned alarm keypad to activate and deactivate an alarm independently from the rest of the warehouse.

All HBC team members with access to the cage or those involved in handling the controlled substances undergo required background checks. KUCHTA advised that before an employee is hired, a criminal history background check is conducted. He stated that the firm has a "zero tolerance" policy with respect to employee pilferage, which means that an employee caught stealing merchandise is immediately terminated from employment. According to the information provided by ROGOS, the employee screening process and

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associated security measures are in compliance with the regulations set forth in Title 21 CFR Parts: 1301.76, 1301.90, 1301.92 and 1301.93.

The subject firm's electronic security is monitored by Sonotrol Security Company. ROGOS advised the investigators that when an alarm sensor is activated in the firm, a signal is transmitted to Sonotrol, who then notifies the South Strabane Township Police Department, located less than five minutes from the firm. After the police department is notified, Sonotrol will call a representative from the subject firm. According to ROGOS, the firm has not had any break-ins or robberies. When an alarm is activated, an audible alarm can be heard throughout the warehouse.

ROGOS stated that, in the event of a power outage, the firm's electronic security is maintained through a battery backup system.

The cage inside the pharmacy room that contains the controlled substances remains locked at all times when not in use. It is permissible for the cage to be unlocked when in use as long as it is being monitored by the coordinator or a member of the management team. Keys to unlock the cage and the alarm activation/deactivation codes are in possession of the HBC operation's management team only.

Prior to a delivery truck arriving or departing from the warehouse facility, exterior mounted video surveillance cameras are viewed at a terminal located in the pharmacy warehouse to ensure there are no unknown persons or vehicles near the facilities loading docks. When a delivery truck is backed into the loading dock platform there is a security device that shrouds the rear of the truck making it impossible to gain access to the pharmacy warehouse room from the building's exterior. Once the vehicle is locked in place, the supervisor closes the exterior door before allowing the driver to enter. The supervisor ensures the holding area is secure and then allows the driver into the holding area. Once the exterior door is closed behind the driver, the supervisor will release the holding area door to allow the driver inside the pharmacy warehouse.

The supervisor will then unlock the padlock that secures the grade-level garage door. If the delivery contains controlled substances, the supervisor unlocks the cage so the product can be taken directly into the

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U.S. Department of Justice  
Drug Enforcement Administration

|   |  |                                   |
|---|--|-----------------------------------|
| <b>REPORT OF INVESTIGATION</b><br><i>(Continuation)</i> | 1. File No.<br>[REDACTED]  | 2. G-DEP Identifier<br>[REDACTED] |
|   | 3. File Title<br>HBC SERVICE CO, 601A Meadowlands<br>Blvd Washington, PA |                                   |
| 4.<br>Page 12 of 16                                     | 6. Date Prepared<br>12-03-2014   |                                   |
| 5. Program Code   |  |                                   |

protected area. The reconciliation takes place inside the cage by the receiver, but excludes the driver. If the driver arrives for pick up, the supervisor follows the same steps indicated for the receiving process before allowing the driver access inside.

On December 2, 2014, the investigators tested all aspects of the subject firm's electronic security. The security was operational and deemed adequate.

KUCHTA informed DIs Sousa and Conlon that the following individuals have routine access to HBC's controlled substance storage cage (ENCLOSURE #10):

| <u>NAME</u>        | <u>SSN</u> | <u>DOB</u> |
|--------------------|------------|------------|
| Jeff BIDDLE        | [REDACTED] | [REDACTED] |
| William CUDIPP     |            |            |
| William HEVIA      |            |            |
| Steven POST        |            |            |
| Matt ROGOS         |            |            |
| Justin BAER        |            |            |
| Brain BECQUET      |            |            |
| Christy HART       |            |            |
| Richard POLAND III |            |            |
| John VINSKI        |            |            |
| Becky WALTON       |            |            |

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|   | 3. File Title<br>HBC SERVICE CO, 601A Meadowlands<br>Blvd Washington, PA |                                   |
| 4.<br>Page 13 of 16                                     | 6. Date Prepared<br>12-03-2014   |                                   |
| 5. Program Code   |  |                                   |

A NADDIS check revealed no derogatory information on these individuals. There is a pool of 45 additional employees who have access to the non-controlled pharmaceutical drugs contained in the pharmacy warehouse, located outside of the Schedule III through V controlled substance cage. These employees undergo the same background checks and have the same level of security as those individual who have access to the controlled substances. When the need arises, on a short term basis, such as an unscheduled illness, a temporary replacement employee maybe transferred from non-controlled drugs to controlled drugs.

#### 9. DUE DILIGENCE

HBC Operations Manager Matt ROGOS advised the investigators that, unlike other drug distributorships, HBC has only one customer, Giant Eagle Pharmacies. All orders for controlled substances are made via dedicated Giant Eagle pharmacy computer systems, whereby only pharmacists can place electronic orders for Schedule III through V controlled substances. ROGOS advised that, at the store level, the pharmacist placing the order may not be the pharmacist on duty when the order is received. When orders are received at the pharmacy, it is the responsibility of a pharmacist and a pharmacy technician to enter controlled substances into the pharmacy inventory.

During the subject firm's last scheduled investigation DI Conlon provided ROGOS with the cite from Title 21 CFR section 1301.74(b) which states, "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from normal patterns and orders of unusual frequency."

ROGOS advised, that currently, HBC and/or Giant Eagle, Inc., its parent company, has no computerized software system to indicate that an order may be suspicious. ROGOS advised that if a Giant Eagle pharmacy were to receive unusually high orders of controlled substances from HBC, deviating from other stores, it would be noticed at the Giant Eagle, Inc. headquarters level. ROGOS stated that he will bring this issue to the

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|   | 3. File Title<br>HBC SERVICE CO, 601A Meadowlands<br>Blvd Washington, PA |                                   |
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attention of Greg CARLSON and Kim REMAS of Giant Eagle's headquarters Controlled Substance Purchasing Unit.

#### 10. MEETING WITH MANAGEMENT

On December 2, 2014, Diversion Investigators Sousa and Conlon meet with ROGOS and KUCHTA to discuss the results of the audit. During this meeting, the investigators advised that both recordkeeping and security are in full compliance with the requirements set forth in Title 21 CFR.

#### 11. VERIFICATIONS

On December 3, 2014, DI Sousa contacted the Giant Eagle Pharmacy located in Robinson Township (*Settlers Ridge*) to verify an order shipped by HBC SERVICE COMPANY, on October 24, 2014. The pharmacist on duty confirmed the purchase of controlled substances from the HBC SERVICE COMPANY.

On December 3, 2014, DI Sousa contacted the Giant Eagle Pharmacy located in Squirrel Hill to verify an order shipped by HBC SERVICE COMPANY, on November 7, 2014. The pharmacist on duty confirmed the purchase of controlled substances from the HBC SERVICE COMPANY.

ARCOS records were utilized to verify purchases of controlled substances by HBC SERVICE COMPANY.

No further action is required at this time. This case is closed.

#### INDEXING

##### 1. HBC SERVICE COMPANY [REDACTED]

(Re: [REDACTED] 12/2014) The subject of a regulatory investigation which resulted in no violations or discrepancies uncovered.

##### 2. ROGOS, Matthew [REDACTED]

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|   | 3. File Title<br>HBC SERVICE CO, 601A Meadowlands<br>Blvd Washington, PA |                                   |
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(Re: [REDACTED] 12/2014) Employed as Operations Manager for HBC SERVICES (DEA # RH0389773). Access to controlled substances.

3. KUCHTA, Robert [REDACTED]

(Re: [REDACTED] 12/2014) Employed as Inventory Manager for HBC SERVICES (DEA # RH0389773). Access to controlled substances.

4. BIDDLE, Jeff [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773). Access to controlled substances.

5. CUDIPP, William [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773). Access to controlled substances.

6. HEVIA, William [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773). Access to controlled substances.

7. POST, Steven [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773). Access to controlled substances.

8. BAER, Justin [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773). Access to controlled substances.

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|   | 3. File Title<br>HBC SERVICE CO, 601A Meadowlands<br>Blvd Washington, PA |                                   |
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| 5. Program Code   |  |                                   |

9. BECQUET, Brian [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773).  
Access to controlled substances.

10. HART, Christy [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773).  
Access to controlled  
substances.

11. POLAND, Richard, III [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773).  
Access to controlled substances.

12. VINSKI, John [REDACTED]

(Re: [REDACTED], 12/2014) Employed at HBC SERVICES (DEA # RH0389773).  
Access to controlled substances.

13. WALTON, Becky [REDACTED]

(Re: [REDACTED] 12/2014) Employed at HBC SERVICES (DEA # RH0389773).  
Access to controlled substances.

Related Files Continued: [REDACTED] [REDACTED]

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U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATIONNOTICE OF INSPECTION  
OF CONTROLLED PREMISES

DEA USE ONLY

FILE NUMBER

|   |  |
|---|--|
| NAME OF INDIVIDUAL<br><i>Joshua Dougherty</i>                     | TITLE<br><i>Pharmacy Supervisor</i>          |
| NAME OF CONTROLLED PREMISES<br>Giant Eagle RX Distribution Center | DEA REGISTRATION NO.<br>RG0491047            |
| NUMBER AND STREET<br>2500 Lovi Road                               | DATE<br><i>5/24/2017</i>                     |
| CITY AND STATE<br>Freedom, PA                                     | ZIP CODE<br>15042                            |
|   | TIME (initial inspection)<br><i>10:45 AM</i> |

## STATEMENT OF RIGHTS

1. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.
2. You have the right to refuse to consent to this inspection.
3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution.
4. You shall be presented with a copy of this Notice of Inspection.
5. You may withdraw your consent at any time during the course of the inspection.

## ACKNOWLEDGMENT AND CONSENT

I, *Joshua Dougherty*, have been advised of the above Statement of Rights  
(Name)  
by DEA DI Michael D. Kupchick, who  
(Title and Name)

has identified himself/herself to me with his/her credentials and presented me with this Notice of Inspection containing a copy of sections 302(f) and 510(a), (b) and (c) of the Controlled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 880(a), (b) and (c)), printed hereon, \* authorizing an inspection of the above-described controlled premises. I hereby acknowledge receipt of this Notice of Inspection. In

addition, I hereby certify that I am the

(President) (Manager) (Owner)

for the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.

I understand what my rights are concerning inspection. No threats or promises have been made to me and no pressure of any kind has been used against me. I voluntarily give consent for inspection of these controlled premises.

(Signature)

(Date)

## WITNESSES:

(signed)

(signed)

(date)

(date)

\* See Reverse

FORM DEA-82 (11-01) Previous editions are obsolete

Enclosure  
Case Number



# Certificate of Registration

Certificate No. 3000009407

(A certificate starting with a number 4, 5 or 6  
does not permit the possession or sale of controlled  
substances or prescription drugs.)

## Drug & Device Registration

132 Kline Plaza  
Suite A  
Harrisburg, PA 17104  
(717) 787-4779

### Category:

Distributor (Prescription)

GIANT EAGLE RX DISTRIBUTION CENTER  
2500 LOVI ROAD  
FREEDOM, PA 15042

The above business is registered in the required category to conduct and maintain a facility in  
accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64,  
approved September 9, 1972.

Issuance Date: October 01, 2015

Expiration Date: The Last Day of October, 2017

*Christine C. Filipovich, MSN, RN*

Christine C. Filipovich, MSN, RN  
Deputy Secretary for Quality Assurance



pennsylvania  
DEPARTMENT OF HEALTH

*Karen M. Murphy, PhD, RN*

Karen M. Murphy, PhD, RN  
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.



## Board of Pharmacy

### CONTROLLED SUBSTANCE PERMIT

July 1, 2017 - June 30, 2018 - Date Issued: June 21, 2017

Giant Eagle Rx Distribution Center

2500 Lovi Road  
Freedom, PA 15042

LICENSE # MI0001031

DEA # RG0491047

Schedule II Narcotic  
Schedule II Non-Narcotic  
Schedule III Narcotic  
Schedule III Non-Narcotic  
Schedule IV All  
Schedule V All

Enclosure

Case Number





## Board of Pharmacy

### WHOLESALE DRUG DISTRIBUTOR PERMIT

July 1, 2017 - June 30, 2018 - Date Issued: March 22, 2017

Giant Eagle Rx Distribution Center

2500 Lovi Road  
Freedom, PA 15042

LICENSE # WD0559761

DEA # RG0491047





State of Ohio

## STATE BOARD OF PHARMACY

77 South High Street, 17th Floor; Columbus, Ohio 43215-6126 TEL: 614/466-4143 FAX: 614/752-4836 EML: [licensing@pharmacy.ohio.gov](mailto:licensing@pharmacy.ohio.gov)

Be it known that the **WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS** named below is duly registered, and is entitled to distribute dangerous drugs at wholesale in the state of Ohio until the expiration date of June 30, 2018.

Identification Number: WHS.012587000-03

SIGN AND KEEP IN A READILY RETRIEVABLE LOCATION AT THIS ADDRESS

RESPONSIBLE PERSON:

ADAM ZAKIN

**GIANT EAGLE RX DISTRIBUTION CENTER**  
2500 LOVI ROAD  
FREEDOM, PA 15042

**SIGNATURE OF RESPONSIBLE PERSON**

Any change of responsible person must be reported within 10 days on a "Notification of Change of Responsible Person" form. Before change of name, address, or ownership, immediately notify the Licensing Department of the State Board of Pharmacy. (see below)

CLASS: Wholesaler/Manufacturer - Category Three  
BUSINESS TYPE: FS - Full Service

-----  
(KEEP THIS SECTION FOR FUTURE REFERENCE)**General Information**

A **CHANGE** in business name, address, ownership (not officers-see next paragraph for officer changes), or category requires **RE-APPLICATION & FEE**. The new application and required fee shall be submitted within thirty (30) days of the change. In the event of an address change, **notify** the Board of Pharmacy **BEFORE** moving any dangerous drugs. [Sections 4729.51 and 4729.52, O.R.C.; Rule 4729-9-16, O.A.C.]. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>, and choose the appropriate application.

*In accordance with paragraph (A)(7) of 4729-9-16 (OAC) (effective January 1, 2009), if a wholesale distributor is incorporated, a criminal records check is required every time there is a change in officers. Contact the board office for the fingerprint cards or you can go to <http://www.ohioattorneygeneral.gov/Business/Services-for-Business/Webcheck> to request fingerprint cards BIM-12-98 (BCI) and FD-258 (FBI)*

**New Officers:** When adding new officers, submit a written notice to the Board including full name, title, date of birth and last four of social security number for each new officer.

Any change of responsible person must be reported within 10 days, on a "Notification of Change of Responsible Person" form. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

**Notify** the Board of Pharmacy in writing **14 days prior to discontinuing business**, whether closing or selling. Written notice [Discontinuing Business form is available at the link below] and state license must be mailed (return receipt requested) or hand delivered to the Board office. [Section 4729.62 O.R.C.; Rule 4729-9-07, O.A.C.]

For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

**Notify** the Board of Pharmacy **of any new** facilities, work or storage areas to be constructed or utilized for dangerous drugs, **or any changes** in operation of the registrant **before** being used or implemented. [Rule 4729-9-16, O.A.C.]

All communications will be done through EMAIL- NOT MAILINGS. Please go to the following webpage to provide the email address that you wish to receive these communications: <https://pharmacy.ohio.gov/UpdateEmailAddress.aspx>

In order to enter your email address in the webpage mentioned above, you will need your login information, which is below.

User ID: 4445445

Password: 759315

Current Email on File: GERXLICENSES@GIANTEAGLE.COM

If you have problems or concerns, please feel free to contact the Board office utilizing the "CONTACT THE BOARD" selection along the left side of the website. Be sure to select "General Licensing Information" as your subject line.

Enclosure  
Case Number

4



State of Ohio



## STATE BOARD OF PHARMACY

77 South High Street, 17th Floor; Columbus, Ohio 43215-6126 TEL: 614/466-4143 FAX: 614/752-4836 EML: [licensing@pharmacy.ohio.gov](mailto:licensing@pharmacy.ohio.gov)

Be it known that the DISTRIBUTOR OF CONTROLLED SUBSTANCES named below is duly registered, and is entitled to distribute controlled substances in the state of Ohio until the expiration date of June 30, 2018.

Identification Number: WCSW.2852

SIGN AND KEEP IN A READILY RETRIEVABLE LOCATION AT THIS ADDRESS

RESPONSIBLE PERSON:

ADAM ZAKIN

GIANT EAGLE RX DISTRIBUTION CENTER  
2500 LOVI ROAD  
FREEDOM, PA 15042

## SIGNATURE OF RESPONSIBLE PERSON

Any change of responsible person must be reported within 10 days on a "Notification of Change of Responsible Person" form. Before change of name, address, or ownership, immediately notify the Licensing Department of the State Board of Pharmacy. (see below)

CLASS: Controlled Substance Wholesaler  
BUSINESS TYPE: FS - Full Service-----  
(KEEP THIS SECTION FOR FUTURE REFERENCE)

## General Information

A **CHANGE** in business name, address, ownership (not officers-see next paragraph for officer changes), or category requires **RE-APPLICATION & FEE**. The new application and required fee shall be submitted within thirty (30) days of the change. In the event of an address change, **notify** the Board of Pharmacy **BEFORE** moving any dangerous drugs. [Sections 4729.51 and 4729.52, O.R.C.; Rule 4729-9-16, O.A.C.]. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>, and choose the appropriate application.*In accordance with paragraph (A)(7) of 4729-9-16 (OAC) (effective January 1, 2009), if a wholesale distributor is incorporated, a criminal records check is required every time there is a change in officers. Contact the board office for the fingerprint cards or you can go to <http://www.ohioattorneygeneral.gov/Business/Services-for-Business/Webcheck> to request fingerprint cards BIM-12-98 (BCI) and FD-258 (FBI)***New Officers:** When adding new officers, submit a written notice to the Board including full name, title, date of birth and last four of social security number for each new officer.Any change of responsible person must be reported within 10 days, on a "Notification of Change of Responsible Person" form. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>**Notify** the Board of Pharmacy in writing 14 days prior to discontinuing business, whether closing or selling. Written notice [Discontinuing Business form is available at the link below] and state license must be mailed (return receipt requested) or hand delivered to the Board office. [Section 4729.62 O.R.C.; Rule 4729-9-07, O.A.C.]  
For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>**Notify** the Board of Pharmacy of **any new** facilities, work or storage areas to be constructed or utilized for dangerous drugs, or **any changes** in operation of the registrant **before** being used or implemented. [Rule 4729-9-16, O.A.C.]All communications will be done through EMAIL- NOT MAILINGS. Please go to the following webpage to provide the email address that you wish to receive these communications: <https://pharmacy.ohio.gov/UpdateEmailAddress.aspx>

In order to enter your email address in the webpage mentioned above, you will need your login information, which is below.

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Password: 759315

Current Email on File: GERXLICENSES@GIANTEAGLE.COM

If you have problems or concerns, please feel free to contact the Board office utilizing the "CONTACT THE BOARD" selection along the left side of the website. Be sure to select "General Licensing Information" as your subject line.

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Drug Enforcement Administration

REPORT OF INVESTIGATION

Page 1 of 19

|   |  |  |                                   |
|---|--|--|-----------------------------------|
| 1. Program Code   | 2. Cross File<br>Related Files   | 3. File No.<br>[REDACTED]  | 4. G-DEP Identifier<br>[REDACTED] |
| 5. By: Michael D Kupchick, DI<br>At: Pittsburgh DO  | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | 6. File Title<br>GIANT EAGLE RX DISTRIBUTION CENTER,<br>Freedom PA |                                   |
| 7. <input checked="" type="checkbox"/> Closed <input checked="" type="checkbox"/> Requested Action Completed<br><input type="checkbox"/> Action Requested By: |  | 8. Date Prepared<br>05-26-2017                                     |                                   |
| 9. Other Officers: DI Rita Esquivel-Blatt   |  |  |                                   |
| 10. Report Re: Case Closing and Cyclic Investigation, GIANT EAGLE RX DISTRIBUTION CENTER,<br>RG0491047, 2500 Lovi Road, Freedom, PA 15042 [REDACTED]          |  |  |                                   |

**SYNOPSIS**

On May 24, 2017, pursuant to the Pittsburgh District Office (PGE DO) cyclic workplan for FY 2018, Diversion Investigators (DI) Michael Kupchick and Rita Esquivel-Blatt conducted an on-site regulatory investigation of GIANT EAGLE RX DISTRIBUTION CENTER, a Division of GIANT EAGLE, INC., located at 2500 Lovi Road, Freedom, PA 15042.

GIANT EAGLE RX DISTRIBUTION CENTER) (DEA # RG0491047, expiration September 30, 2018, [REDACTED]) is registered with DEA as a distributor to handle controlled substances in schedules 2, 3, 3N, 4 and 5. The onsite portion of this investigation began and concluded on May 24<sup>th</sup>, 2017 and concluded on August 1, 2017.

This investigation revealed no discrepancies with respect to recordkeeping or security. The audit of controlled substances revealed a shortage of 1,000 Lorazepam 1mg tablets.

No further action is required. This case is closed.

|                               |  |                        |
|-------------------------------|--|------------------------|
| 11. Distribution:<br>Division | 12. Signature (Agent)<br><br>/s/ Michael D Kupchick, DI          | 13. Date<br>05-26-2017 |
| District                      | 14. Approved (Name and Title)<br>/s/ Lewis D Colosimo, Acting GS | 15. Date<br>11-08-2017 |
| Other [REDACTED]              |  |                        |

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|   | 3. File Title<br>GIANT EAGLE RX DISTRIBUTION CENTER,<br>Freedom PA |                                   |
| 4.<br>Page 2 of 19                                      |  |                                   |
| 5. Program Code   | 6. Date Prepared<br>05-26-2017                                     |                                   |

#### ENCLOSURES

1. DEA-82 - Notice of Inspection
2. PA Dept of Health Drug Distributorship/ Wholesaler Certificates
3. West VA Pharmacy Controlled Substance/ Drug Distributorship Permit
4. State of Ohio Pharmacy Drug Distributorship Certificates
5. DEA Biennial Inventory
6. Closing Inventory
7. Audit Computation Chart
8. GERXDC Inventory records
9. DEA 222 and DEAE222 Order Forms
10. GERXDC Purchase records
11. GERXDC Sales Records
12. ARCOS Reports
13. Floor Plan
14. CSOS instructions

#### DETAILS

##### **1. BASIS OF INVESTIGATION**

On May 24, 2017, pursuant to the Pittsburgh District Office (PGH DO) cyclic work plan for FY 2018, Diversion Investigators (DI) Michael Kupchick and Rita Esquivel-Blatt conducted an on-site regulatory investigation of GIANT EAGLE RX DISTRIBUTION CENTER, a Division of GIANT EAGLE, INC., located at 2500 Levi Road, Freedom, PA 15042

GIANT EAGLE RX DISTRIBUTION CENTER INC. (DEA # RG0491047, expiration September 30, 2018, [REDACTED]) is registered with DEA as a distributor to handle controlled substances in schedules 2, 2N, 3, 3N, 4 and 5. The onsite portion of this investigation began on May 24, 2017 and concluded on August 1, 2017, with a meeting with management.

##### **2. SUBJECT FIRM'S BACKGROUND**

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|   | 3. File Title<br>GIANT EAGLE RX DISTRIBUTION CENTER,<br>Freedom, PA |                                   |
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GIANT EAGLE RX DISTRIBUTION CENTER, to be referred to as GERXDC, is located at 2500 Lovi Road, Freedom, PA 15042, distributes Scheduled II controlled substances to approximately 220 Giant Eagle supermarkets located in Pennsylvania, West Virginia, and Ohio. Giant Eagle pharmacies are the subject firm's sole customer base. GERXDC CENTER had \$157,000,000 dollars in sales during 2017, of which controlled substances accounted for less than one percent.

GERXDC was approved as a drug distributor on January 8, 2016 and issued DEA registration number RG0491047 under DEA file number [REDACTED]. This registration expires on September 30, 2018.

GERXDC is licensed with the Commonwealth of Pennsylvania, Department of Health, as a distributor of prescription medicine, Certificate Number 300C009407, which expires on October 31, 2017 (*ENCLOSURE #2*). GERXDC is licensed with the State of West Virginia, Board of Pharmacy as a wholesale drug distributor under license number WD0559761, which expires on June 30, 2018 (*ENCLOSURE #3*). HBC is licensed with the State of Ohio, Board of Pharmacy as a distributor of controlled substances under ID Number WHS.C12587000-CB. This registration expires on June 30, 2018 (*ENCLOSURE #4*).

### 3. PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

On May 24, 2017, Investigators Kupchick and Esquivel-Blatt presented their credentials and a Notice of Inspection (DEA Form 82) (*ENCLOSURE #1*) to Joshua DOUGHERTY, GERXDC Pharmacy Supervisor, for the subject firm. DOUGHERTY read and signed the DEA Form 82, giving his consent for the inspection to proceed. DOUGHERTY stated that he is responsible for the subject firm's inventory operations, with respect to controlled substances. DOUGHERTY provided all the necessary records and information required to conduct this investigation.

### 4. PRINCIPALS OF THE FIRM

Laura Karet, President and CEO  
Mark J. Minnaugh, CFO

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John Lucot, COO  
Adam Zakin, Sr. Director of Pharmacy Administration  
George Chunderlik, Manager of Pharmacy Compliance

NADDIS queries on these individuals did not reveal any negative information.

#### 5. SCOPE OF INVESTIGATION

The on-site portion of the investigation commenced on May 24, 2017, and concluded on August 1, 2017, with a meeting with management.

An accountability of Oxycodone 30 mg tablets (Schedule II, drug code 2100) Morphine Sulfate ER 20 mg tablets (Schedule II, drug code 2784) Buprenorphine/Naloxone 8-2 mg tablets (Schedule III, drug code 9064) Buprenorphine/Naloxone 2-0.5 mg tablets (Schedule III, drug code 9064), Buprenorphine 8mg tablets (Schedule III, drug code 9064), Lorazepam 1mg tablets (Schedule IV, drug code 2885), Diazepam 5 mg tablets (Schedule IV, drug code 2765), and Acetaminophen/Sodium Phosphate 120mg/12mg/5ml (Schedule V, was conducted for the period March 23, 2016 (BOB), through May 24, 2017 (BOB).

The results of this audit are listed below and documented on the attached computation chart (ENCLOSURE #7). This accountability audit revealed a shortage of 1,000 lorazepam 1mg tablets, 0.02%. According to Chunderlik, the bottle of 1000 lorazepam 1mg tablets, was placed in the morgue area of GERXDC. Chunderlik stated that the morgue area of GERXDC is where expired and or damaged controlled substances and all other pharmaceuticals are placed while awaiting transfer to a reverse distributor for destruction. (All figures are in number of bottles/containers)

HBC SERVICES

DEA # RH0389773

Initial Inventory Date:

BOB 03/23/2016

Closing Inventory Date:

COB 05/24/2017

DATE 12/2/2014

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| Drug Name, Strength, Form       | Initial Inventory | Received         | Total Accountable For | Closing Inventory | Distributed/Transferred | Total Accounted For | Total Difference | % Difference  |
|---------------------------------|-------------------|------------------|-----------------------|-------------------|-------------------------|---------------------|------------------|---------------|
| Oxycodone 30 mg tabs            | 87,300            | 465,600          | 552,900               | 39,800            | 513,100                 | 552,900             | 0                | 0             |
| Morphine Sulphate ER 20 mg      | 1,900             | 18,000           | 19,900                | 2,900             | 17,000                  | 19,900              | 0                | 0             |
| Buprenorphine/Naloxone 8-2 mg   | 11,370            | 84,240           | 95,610                | 0                 | 95,610                  | 95,610              | 0                | 0             |
| Buprenorphine/Naloxone 2-05mg   | 0                 | 3,600            | 3,600                 | 2,130             | 1,470                   | 3,600               | 0                | 0             |
| Buprenorphine 8mg               | 6,180             | 40,320           | 46,500                | 1,050             | 45,450                  | 46,599              | 0                | 0             |
| Diazepam 5mg tablets            | 86,000            | 1,152,000        | 1,238,000             | 27,000            | 1,211,000               | 1,238,000           | 0                | 0             |
| Lorazepam 1mg Tab               | <u>154,000</u>    | <u>3,348,000</u> | <u>3,502,000</u>      | <u>43,000</u>     | <u>3,458,000</u>        | <u>3,501,000</u>    | <u>-1000</u>     | <u>-0.02%</u> |
| Acetaminaphene/Sodium Phosphate | 0                 | 56,760           | 56,760                | 8514              | 48,246                  | 56,760              | 0                | 0             |

## 6. RECORDKEEPING

### Biennial Inventory:

A biennial inventory, as required by Title 21 C.F.R. 1304.11 (c), was taken by the subject firm on March 21, 2017. (ENCLOSURE #5)

### Initial Inventory:

The figures for the initial inventory portion of the audit were taken from the firm's "NDC Audit Item Inventory" report dated March 23, 2016. Among other internal data, this computer-generated report captures the date, drug name, strength, bottle size, and quantity on hand for each controlled substance. CHUNDERLIK provided these figures as factual for the purposes of the audit's initial inventory. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

### Closing Inventory:

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On May 24, 2017, Dis Kupchick and Esquivel-Blatt conducted a physical count, closing inventory, which was witnessed by TEYSSIER. (Enclosure #6) This physical count was compared against the subject firm's "Item Inquiry" report which is a daily control substance inventory report, sorted by item number associated with each separate controlled substance. Among other internal data, this computer-generated report captures the date, time, drug name, strength, bottle size, and quantity on hand for each controlled substance. These figures were compared against the actual physical count and no discrepancies were found. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

**Receiving/Purchasing Records:**

GERXDC maintains electronic copies of DEA-222 Order Forms via CSOS. DTs Kupchick and Esquivel-Blatt reviewed CSOS Order Forms, which were completed in accordance with 21 C.F.R. 1305.13. The subject firm's purchase records are further documented via the original purchase invoices from the drug suppliers, which are physically maintained and entered into a computer database by drug item number. These figures are captured on the subject firm's "NDC Audit Item Inventory Detail" report, a computer-generated report which, among other internal data, captures a complete, daily perpetual inventory of purchases and distributions of a particular controlled substance by date range (ENCLOSURE #8). A random selection of several purchases were taken from the "NDC Audit Item Inventory Detail" report, and compared against the original source document/purchase invoices for accuracy. No discrepancies were noted. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).

It should be noted that although the subject firm's drug distribution warehouse has computerized access to the "NDC Audit Item Inventory Detail" report, in order to compare this report against the original source document/purchase invoices, the investigators had to travel to the subject firm's corporate headquarters located at the RIDC Industrial Park, 101 Kappa Drive, Bldg. III, Pittsburgh, PA 15238. All purchases are a function of a centralized purchasing unit base at the subject firm's corporate headquarters.

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On August 1, 2017, the investigators reviewed these records with Chunderlik. No discrepancies were found.

It should be noted that the subject firm submitted a written request for authorization for central recordkeeping for the purchase records to be physically stored at its corporate headquarters during the cyclic investigation conducted in 2011 under file number [REDACTED]

#### CSOS

GERXDC began using CSOS in March 2015 to electronically order all of their CII controlled substances. According to CHUNDERLIK all CSOS orders must be submitted by only a pharmacist by 10:00 am with a limit of 1 order per store per day. When an order is received, the eDEA222 must be printed and completely filled out as to quantities received and signed by the pharmacist. CHUNDERLIK provided investigators with a copy of GERXDC CSOS procedures. (Enclosure 14)

#### Sales/Distribution Records:

Since GERXDC is a division of Giant Eagle Supermarkets, its sole customer base is 220 Giant Eagle pharmacies located throughout PA, W.VA, and OH. Sales are initiated at the store level and are computer-generated from the individual store via CSOS and transmitted to the subject firm on a daily basis. GERXDC maintains electronic copies of DEA-222 Order Forms via CSOS. DI's Kupchick and Esquivel-Blatt reviewed CSOS Order Forms, which were completed in accordance with 21 C.F.R. 1305.13. DI's Kupchick and Esquivel-Blatt also reviewed GERXDC internal "Item Invoice Report." These computer-generated invoices capture information such as pharmacy location, DEA number, date of distribution, drug, strength and quantity sold (ENCLOSURE #8). These distribution transactions document daily distributions, within a specified date range, of each particular controlled substance to all customers. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).

#### Damaged/Returned Items:

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There were no returned items noted during the audit period. The subject firm utilizes Capital Returns as its reverse distributor in order to destroy controlled substances. There were no destructions of controlled substances noted during the audit period.

#### 7. ARCOS

Prior to conducting the onsite inspection, DI's Kupchick and Esquivel-Blatt reviewed an ARCOS print out of the pre-selected controlled substances to be audited. The information contained in ARCOS was utilized to verify purchase information supplied by the subject firm during the audit period. No discrepancies were noted. GERXDC is working with ARCOS to correct the 327 error records. According to the ARCOS unit, GERXDC is submitting the ARCOS reports in a timely manner but that ARCOS was/is experiencing problems with the ARCOS EDI upload facility.

#### 8. SECURITY

GERXDC, located in an industrial park (Tri-County Commerce Park) in New Sewickley Township, occupies 13,515 square feet of a 210,000 square foot building constructed of poured reinforced concrete, steel, and brick. Other occupants of the building are limited to Giant Eagle entities such as the Giant Eagle Pharmacy (Central Fill, no walk-in business - DEA Number FG5586447), Giant Eagle fresh foods department, and Giant Eagle storage of health and beauty supplies. Operating hours for the GERXDC will be 5:00 a.m. to 12:30 a.m., Monday through Saturday. GERXDC maintains sufficient external lighting to identify delivery drivers and trucks, as well as to light areas that are under 24 hour video surveillance.

Access to the GERXDC is limited to identifiable employees who have direct, day-to-day functions within the GERXDC (i.e. receiving, replenishment, stocking, and selection). Key FOBs/badges are required to enter and exit the GERXDC. The Key FOBs/badges also allow GERXDC management to restrict unauthorized access into the GERSDX, and further limit access to the firm's cage and vault.

All employees with access to the firm's cage and vault and those involved

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in handling Schedule 2-5 controlled substances must undergo the required background checks associated with the following 21 CFR sites: 1301.76, 1301.90, 1301.92, and 1301.93.

The cage and vault will be locked when not in use. It will be permissible for the cage to be unlocked when it is in use as long as it is being monitored by an authorized member of the GERXDC operation's management team. Keys to unlock the cage and vault will be in the possession of the operation's management.

GERXDC has multiple video surveillance cameras in the cage/vault, providing adequate monitoring of any employee movement while in the cage/vault.

Any visitor to GERXDC must first sign the Visitor's Log upon entering the facility. A visitor's admittance into the facility is permitted only when the visitor is accompanied by a member of the GERXDC operation's management team. The visitor must be supervised at all times. At no time will a visitor be unsupervised while in the GERXDC production area where items, including controlled substances, are store, received, or distributed.

In the event of a power loss, the GERXDC has an industrial-grade backup generator to ensure continuing operations.

The firm's electronic security is monitored by Sonitrol Security Systems, Inc (Sonitrol). Kevin Householder of Sonitrol informed DI Kupchick that alarm signals are transmitted from GERXDC to Sonitrol through a static IP, with a cellular backup. Householder stated that both forms of transmission are under constant supervision so that any tampering would be immediately detected. During non-operating hours, if the GERXDC or cage/vault alarm is activated, Sonitrol will contact the local police department (New Sewickley Township Police Department), as well as the GERXDC warehouse call list, which includes GERXDC Loss Prevention personnel, to inform management of the alarm activation. After GERXDC management investigates the matter, they will contact Sonitrol to inform them of the result of their investigation.

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On May 24, 2017, investigators tested the cage and vault electronic security. This test revealed that an audible alarm could be heard throughout the GERXDC upon unauthorized entry to the cage and vault. The attached results of the test, provided by Sonitrol Security Systems, revealed the security was deemed operational.

#### CAGE SPECIFICATIONS

All Schedule 3-5 controlled substances handled by GERXDC are stored in a cage measuring 46'5" x 27'8" x 29'1" (height), with the cage walls constructed of #10 gauge steel fabric mounted on 2" diameter posts. The placement of the posts and the fence openings are compliant with 21 CFR Part 1301.72. An examination of the fencing bolts revealed they were welded/brazed as required by this CFR site. The cage's ceiling and entrance doors are constructed of similar material as the cage's walls. The cage is equipped with self-locking doors; all cage doors are equipped with contact switches. Motion sensors and cameras are strategically positioned to provide adequate coverage.

All elements of this cage appear to meet the requirement specified in 21 CFR 1301.72(b) (4).

#### VAULT SPECIFICATIONS

All Schedule 2 controlled substances handled by GERXDC are stored in a vault measuring 38'8" x 40'2" x 29'1" (height). The walls, floor, and ceiling are constructed of 8" of poured concrete reinforced with #4 rebar tied 6 inches on center. The vault is equipped with a self-closing, self-locking day gate. The vault door, weighing over 4,000 pounds, is a metal AR5 security vault door manufactured by Overly Door Company, serial number M-5-1054. The vault is equipped with a combination lock. Motion sensors and cameras are strategically positioned in the vault to provide adequate coverage.

#### RECEIVING

GERXDC primary suppliers of controlled substances will be MCKESSON DRUG.

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All controlled substances delivered to the GERXDC must enter the building through the receiving man-doors #1 and #2, where they will be identified at the point of entry, and transported (by authorized personnel) approximately 100 feet into a secure area within the GERXDC. An operations manager is responsible for making sure the delivery of controlled substances into the building is secure, and checks the bill of lading to ensure the correct purchase orders have been received. When the shipment has been inspected, the controlled substances are transported directly to the cage/vault area. Video monitoring records the entire travel path from the receiving dock to the cage/vault.

#### STORAGE

All controlled substances are stored in a secure cage or vault fully described elsewhere in this report. As outlined in the attached "Inventory Control - Suspected Loss Policy" - all generic controlled substances are cycle counted two times per week, while name brand controlled substances are counted nightly after selection is completed. The attached policy details outline other inventory counts and controls performed at GERXDC.

Inventory discrepancies and reports of used, tampered, or opened products are reported to management for investigation. Management will determine if the loss is significant. Criteria for a significant loss can include, but are not limited to the following:

- Any loss of a controlled substance.
- Discrepancies of five(5) percent or greater of the expected on-hand quantity.
- Repeated discrepancies of the same product within a rolling thirty (30) day period.
- Dollar value losses that exceed five hundred dollars (\$500.00) per occurrence.

Significant losses will be reported to DEA upon discovery.

#### SHIPPING

Upon completion of product selection, completed totes are stacked onto

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outbound pallets and prepared for shipping. An authorized employee scans each tote label and attaches all tote labels that are on the pallet to a pallet license plate number. The tote count per pallet is then recorded and documentation is printed for shipping verification. Each outgoing shipment/s are inspected for identity of the drug product, and the container is inspected to ensure no damage has occurred. When the outbound carrier arrives at GERXDC, a manager or supervisor supervises the loading of the pallets. Outbound paperwork will be taken to the loading door, and the manager or supervisor and outbound driver verifys the count of totes on each pallet, as well as the number of pallets to be shipped. Pallets/totes are also inspected at this time for any sign of visual damage or tampering. The driver's and manager's signatures are written on the bill of lading indicating that the counts are correct. If the counts are not correct, the manager will investigate the matter. The Warehouse Operations Manager or GERXDC Supervisor performs and document random audits for outgoing shipments. Video surveillance monitoring will cover the path from the cage/vault to the loading door.

Prior to a delivery truck arriving or departing from the warehouse facility, exterior mounted video surveillance cameras are viewed at a terminal located in the pharmacy warehouse to ensure there are no unknown persons or vehicles near the facilities loading docks. When a delivery truck is backed into the loading dock platform there is a security device that shrouds the rear of the truck making it impossible to gain access to the pharmacy warehouse room from the building's exterior. Once the vehicle is locked in place, the supervisor closes the exterior door before allowing the driver to enter. The supervisor ensures the holding area is secure and then allows the driver into the holding area. Once the exterior door is closed behind the driver, the supervisor will release the holding area door to allow the driver inside the pharmacy warehouse.

The supervisor will then unlock the padlock that secures the grade-level garage door. If the delivery contains controlled substances, the supervisor unlocks the cage so the product can be taken directly into the protected area. The reconciliation takes place inside the cage by the receiver, but excludes the driver. If the driver arrives for pick up, the supervisor follows the same steps indicated for the receiving process before allowing the driver access inside.

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CHUNDERLIK informed DTs Kupchick and Esquivel-Blatt that the following individuals have routine access to GERXDCs controlled substance storage cage (ENCLOSURE #10):

| Name                 | Social Security Number | Date of Birth |
|----------------------|------------------------|---------------|
| Joshua Dougherty     | [REDACTED]             |               |
| Mat Hubert           |                        |               |
| Jacob Teyssier       |                        |               |
| Dave Hubsch          |                        |               |
| Sarah Brianne Pappas |                        |               |

A NADDIS check revealed no derogatory information on these individuals.

Talon Logistics, the exclusive private carrier for Giant Eagle, is the primary carrier for GERXDC. Other private carriers used by GERXDC are Prestige Delivery Systems and Aim Dedicated Logistics. As per 21 CFR 1301.74(e), the firm is responsible for selecting a common or contract carrier which provides adequate security to guard against in-transit losses. HBC has used all three carriers identified above. As noted in the Theft/Loss section of this report, a review of DEA's Theft/Loss database revealed HBC has filed only four DEA Form 106s (Report of Theft or Loss of Controlled Substances) since they were approved by DEA as a distributor in 2016: one loss was attributed to employee pilferage (his employment was terminated); three were described as in-transit losses. HBC appropriately documented on each of the forms security measures they took to prevent or limit future thefts/losses.

#### Customer Authentication

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To ensure that controlled substances are distributed only to legitimate, properly licensed customers, GERXDC has established a "Customer Authentication" policy (**Attachment 10**). This policy is summarized as follows: The GERXDC only services Giant Eagle Pharmacies which are owned by Giant Eagle, Inc. If, for any reason, a Giant Eagle Pharmacy is not licensed to receive Legend drug products or controlled substances, the GERXDC will no longer service the pharmacy.

GERXDC maintains copies of all customer licensure - state pharmacy licenses and DEA registration certificates. Licensing information will be verified through state agencies websites, as well as the DEA website ([www.dea diversion.usdoj](http://www.dea diversion.usdoj)). If at any time a pharmacy is not licensed by the DEA and applicable State Board of Pharmacy, no Legend or controlled substances will be sold to them. GERXDC will report to the State Board of Pharmacy, DEA, and the FDA within three (3) business days if they are unable to authenticate a customer.

#### Suspicious Orders

GERXDC has developed an Order Monitoring System (OMS) to assist in detecting suspicious orders placed by any of their customers. The OMS algorithm generates flags based on monthly thresholds and ordering characteristics specific to the following:

- Pharmacy location
- Controlled Substance/Chemical
- Generic Product Indicator
- National Drug Code
- Week of the month
- Ordering patterns

Flagged controlled substance orders are generated through a daily report. The flagged orders cannot be filled until investigated and resolved by the OMS team, which includes designated individuals from Pharmacy Procurement, Pharmacy Operations, and the Loss Prevention Pharmacy Analyst. Pharmacy Procurement blocks the target drug from the identified pharmacy's order during the investigation. Pharmacy Procurement team members can utilize a

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| <b>REPORT OF INVESTIGATION</b><br><i>(Continuation)</i> | 1. File No.<br>[REDACTED]  | 2. G-DEP Identifier<br>[REDACTED] |
|   | 3. File Title<br>GIANT EAGLE RX DISTRIBUTION CENTER,<br>Freedom PA |                                   |
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computer software feature called Supplylogix Pinpoint Order or the drug management function of the pharmacy dispensing system to block the ability of a pharmacy to order the drug or chemical under investigation. GERXDC quarantines the product from the flagged store's order until the conclusion of the investigation. Orders for flagged stores are blocked through CSOS until investigated and resolved.

Investigations of flagged orders can include, but are not limited to the following:

- Purchasing patterns
- Dispensing patterns
- Percentage of controlled substance prescriptions
- Percentage of target controlled substances (e.g. Oxycodone, hydrocodone, buprenorphine)
- Form of payment (Third party or cash)
- Histories and patterns of prescribing physicians
- Interviews of store pharmacists and technicians
- Loss Prevention review of store surveillance video
- Review of Supplylogix Pinpoint Audit (used to identify pharmacies that are at risk for inventory built, I.e. purchases exceed dispensing)
- Review of Supplylogix Pinpoint Monitor (used to identify at risk purchasing patterns)

If the OMS team determines the flagged order is not suspicious, the orders are cleared for distribution by the GERXDC. If the order is deemed to be suspicious, the flagged item remains blocked, and the DEA is notified in writing within one business day of the determination. Law enforcement (DEA/State or local police) may also be notified.

Documentation of the above-described investigations will be retained in readily retrievable form for at least two years. A sample form used to document the investigation is attached to this report. The OMS policy and processes are reviewed quarterly (for effectiveness and quality) by the OMS Review Committee consisting of several individuals listed in the attached policy.

A NADDIS check revealed no derogatory information on these individuals.

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There is a pool of 45 additional employees who have access to the non-controlled pharmaceutical drugs contained in the pharmacy warehouse, located outside of the Schedule III through V controlled substance cage. These employees undergo the same background checks and have the same level of security as those individual who have access to the controlled substances. When the need arises, on a short term basis, such as an unscheduled illness, a temporary replacement employee maybe transferred from non-controlled drugs to controlled drugs.

#### 9. DUE DILIGENCE

GIANT EAGLE RX DISTRIBUTION CENTER Manager Joshua DAUGHERTY advised the investigators that, unlike other drug distributorships, GIANT EAGLE RX DISTRIBUTION CENTER has only one customer, Giant Eagle Pharmacies. All orders for controlled substances are made via dedicated Giant Eagle pharmacy computer systems, whereby only pharmacists can place electronic orders for Schedule III through V controlled substances. DAUGHERTY advised that, at the store level, the pharmacist placing the order may not be the pharmacist on duty when the order is received. When orders are received at the pharmacy, it is the responsibility of a pharmacist and a pharmacy technician to enter controlled substances into the pharmacy inventory.

CHUNDERLIK advised investigators that GERXDC has developed an Order Monitoring System (OMS) to assist in detecting suspicious orders placed by any of their customers. The OMS algorithm generates flags based on monthly thresholds and specific ordering characteristics.

#### 10. MEETING WITH MANAGEMENT

On August 1, 2017, Diversion Investigators Kupchick and Esquivel-Blatt meet with CHUNDERLIK to discuss the results of the audit. During this meeting, the investigators advised that both recordkeeping and security are in full compliance with the requirements set forth in Title 21 CFR.

#### 11. VERIFICATIONS

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ARCOS records were utilized to verify purchases of controlled substances by GERXDC. No further action is required at this time.

This case is closed.

## 12. SPECIAL ASSIGNMENTS

No special assignments were completed.

## INDEXING

1. GIANT EAGLE RX DISTRIBUTION CENTER  
2500 Lovi Road, Freedom, PA 15042  
DEA# RG0491047

\* Subject of Cyclic Investigation on May 24, 2017 \*

2. DOUGHERTY, Joshua

\* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

3. TEYSSIER, Jacob

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\* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

4. HUBERT, Mal [REDACTED]  
[REDACTED]

\* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

5. HUBSCH, David [REDACTED]  
[REDACTED]

\* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

6. PAPPAS, Sarah Brianna [REDACTED]  
[REDACTED]

\* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

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